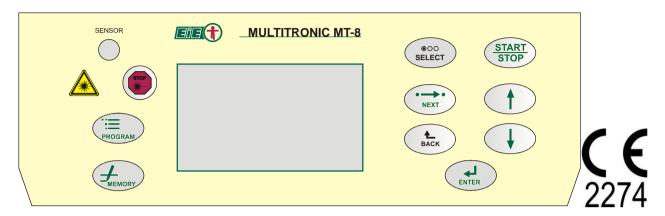
MULTITRONIC MT-6

Double-Channel Electrotherapy, Ultrasound and Laser Biostimulation



INSTRUCTIONS FOR USE

NOTICE! PROTECT THE MANUAL FROM LOSS. THIS MANUAL IS PART OF THE EQUIPMENT

NUMBER:

In the case of loss, instructions are sold after this number is given.

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MANUFACTURER: Elektronika i Elektromedycyna M.Lewandowski Sp.J. 05–402 OTWOCK, ul. Zaciszna 2, tel./fax +48 22 779 42 84; tel. +48 22 710 08 39 www.eie.com.pl e-mail: office@eie.com.pl

WARRANTY CARD

Name and model of the product: MULTITR (ONIC MT-6
Serial number	Date of production
Warranty period: 24 months from the date of	purchase.
3. Exploitation of the product must be co	the fully fit equipment to the customer. In a standard and signed by the seller. Inducted according to the instructions for use. Is will be done by the manufacturer or by the
exploitation (electrodes, cables, bands 2. Mechanical damages which did not ris	se from the fault of the producer. and the like), which can happen under the
The warranty ceases to be valid in the case of the first of the warranty period. 2. Lack of required periodic technical tests. 3. Repairs done by the user or an unqual technical tests.	sts. Ilified service.
All customer complaints should be sent to th	e above address.
	Stamp and signature of the manufacturer
Date of purchase	Stamp and signature of the seller

Confirmations of technical service

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I. APPLICATION

I.1. Meaning of symbols used in this manual.

<u>WARNING:</u> This symbol indicates that it is absolutely necessary to acquaint with and remember the following information regarding safety of use of the device. Failure to consider such warnings may cause deterioration of health or even death.

IMPORTANT: This symbol indicates essential advice helping to prevent the damage of the device or equipment as well as the important general information.

NOTICE: This symbol indicates useful hints making the operating of the device easier.

I.2. Intended purpose of the device

MULTITRONIC MT-6 is intended for use in professional healthcare facilities by a qualified physiotherapy technician.

MULTITRONIC MT-6 is a modern, microprocessor controlled unit for double-channel electrotherapy, ultrasound and laser biostimulation. It has the state-of-the-art user interface (a colour graphic screen with touch panel). It can work with various types of laser probes emitting red and infrared light, ultrasound heads of different sizes and magnetic field applicators.

A detailed description of the therapeutic indications can be found in chapter VII "MEDICAL DESCRIPTION".

WARNING: Any treatment with MULTITRONIC MT-6 should be performed carefully by a qualified physiotherapy technician.

<u>WARNING:</u> The manufacturer takes no responsibility for using this device in violation of the instructions for use recommendations, especially if the obligatory servicing is neglected or the device is used by the unqualified staff.

<u>WARNING:</u> The ultrasound heads (applicators, probes) are calibrated and dedicated to an individual device. Using the heads with other devices without the calibration can result in using wrong treatment parameters. DO NOT use the heads with another device without previous calibration by the manufacturer.

IMPORTANT: Device is an electrical device like a TV-set, radio or hair dryer so the operator should observe the basic safety precautions:

- do not pour water or other liquids on the device
- do not open the device's case
- do not cover the ventilation vents
- do not expose the device to shaking, moisture or dust.

NOTICE: The device has pre-programmed average treatment parameters for typical diseases (PROGRAM function) and has the option of their individual adjustment. You can also save settings of treatment parameters individually selected by the operator (MEMORY function).

I.3. Other symbols used on the device

ON THE DEVICE				
C€	CE mark	MD	Medical device	
UDI	Unique device identifier		Manufacturer	
~~	Date of manufacture	SN	Serial number	
REF	Catalogue number	\triangle	Caution	
☀	Electrical device type BF		Fuse	
[]i	Consult instructions for use or consult electronic instructions for use		Door emergency switch connection	
	Laser radiation symbol		Equipment should be disposed of according to the regulations for disposing of electrical devices	
ON THE PACKAGE				
-x'Cmin	Maximum allowed temperature range	**	Keep dry	
x kg max.	The maximum allowable load on the package	<u> </u>	This side up	

II. TECHNICAL SPECIFICATION

II.1. Nominal operating conditions

Heating time
Time of continuous work
1 min
24 h

Power supply (single phase)
 ~230 V 10%, 50 Hz, 70 VA

Laser device class

Insulation class
 Ambient temperature
 Relative humidity
 Atmospheric pressure
 I type BF
 10°C ÷ 40°C
 up to 85%
 780-1060 hPa

II.2. Additional specifications

• Dimensions 335 x 270 x 125 mm

Weight (without accessories)
 3,4 kg

II.3. Technical data - laser

NOTICE: The powers and energies of the laser light below are given with accuracy $\pm 20\%$.

NOTICE: Times and frequencies below are given with accuracy ± 10%.

S-1N point probe (pulsed) 50 mW / IR:

 $\begin{array}{lll} \bullet & \text{wavelength} & 905 \text{ nm} \pm 10 \text{ nm} \\ \bullet & \text{mean power (depending on frequency)} & 50 \text{ mW} \\ \bullet & \text{pulse power} & 50 \text{ W} \\ \bullet & \text{pulse energy} & 10 \text{ } \mu\text{J} \\ \bullet & \text{pulse width} & 200 \text{ ns} \\ \end{array}$

frequency of pulse repetition
 5 ÷ 5000 Hz

S-2N point probe 40 mW / R:

• wavelength 660 nm ±10 nm

continuous power
 40 mW

modulated work mode:

range of power (adjusted)
 frequency of pulse repetition
 1 ÷ 40 mW
 5 ÷ 9999 Hz

S-2B point probe 80 mW / R:

• wavelength 660 nm ±10 nm

• continuous power 80 mW

modulated work mode:

range of power (adjusted)
 frequency of pulse repetition
 1 ÷ 80 mW
 5 ÷ 9999 Hz

S-3N point probe 400 mW / IR:

• wavelength 808 nm \pm 20 nm

continuous power
 400 mW

modulated work mode:

range of power (adjusted)
 frequency of pulse repetition
 1 ÷ 400 mW
 5 ÷ 9999 Hz

SP-1B cluste	probe 720	mW/R:
--------------	-----------	-------

• total continuous power 720 mW

number of diodes

• wavelength 660 nm ±10 nm

single diode power
 effective area of treatment
 50 cm²

modulated work mode:

range of power (adjusted)
 frequency of pulse repetition
 10 ÷ 720 mW
 5 ÷ 9999 Hz

SP-2B cluster probe 1040 mW / R+IR:

total continuous power
 number of diodes
 R wavelength
 1040 mW
 5 (R) + 4 (IR)
 660 nm ±10 nm

R single diode power
 80 mW

• IR wavelength 808 nm ±10 nm

IR single diode power
 effective area of treatment
 50 cm²

modulated work mode:

range of power (adjusted)
 frequency of pulse repetition
 10 ÷ 1040 mW
 5 ÷ 9999 Hz

SP-3 cluster probe 1440 mW / IR:

total continuous power
 1440 mW

number of diodes

• wavelength 808 nm ±20 nm

single diode power
 effective area of treatment
 50 cm²

modulated work mode:

range of power (adjusted)
 frequency of pulse repetition
 10 ÷ 1440 mW
 5 ÷ 9999 Hz

II.4. Technical data – ultrasound

NOTICE: The ultrasonic powers below are given with accuracy ± 20%.

NOTICE: Times and frequencies below are given with accuracy ± 10%.

SU-1 treatment head

effective treatment area
 ultrasound frequency
 power density (continuous mode)
 peak power density (modulated mode)
 type of beam
 ingress protection code
 1,33 cm²
 1 MHz lub 3,3 MHz
 0,1 ÷ 2,5 W/cm²
 0,1 ÷ 3 W/cm²
 collimated
 IPX7

Ingress protection code
 IFA7
 BNR
 < 6:1

SU-5 treatment head

effective treatment area
 ultrasound frequency
 power density (continuous mode)
 5 cm²
 1 MHz lub 3,3 MHz
 0,1 ÷ 2,5 W/cm²

peak power density (modulated mode)
 type of beam
 0,1 ÷ 3 W/cm² collimated

ingress protection codeBNRIPX76:1

SUP-6 treatment head

• effective treatment area 6x3 cm²

ultrasound frequency
 power density (continuous mode)
 peak power density (modulated mode)
 1 MHz lub 3,3 MHz
 0,1 ÷ 2,5 W/cm²
 0,1 ÷ 2,5 W/cm²

type of beam collimated

ingress protection codeBNRIPX76:1

Device parameters

max. continuous power
pulse frequency
12,5 W
10 – 150 Hz

working modes continuous or pulsed

duty factor 5 – 100%
 digital timer for treatment 30 s ÷ 30 min

NOTICE: In modulating mode of operation, the maximum continuous power density must not be exceeded.

NOTICE: If another treatment is started in addition to the ultrasound treatment, the maximum power (continuous and modulated) is limited to 1 W/cm².

II.5. Technical data – electrotherapy

NOTICE: The values of currents and voltages below are given with accuracy ± 20%.

NOTICE: Times and frequencies below are given with accuracy ± 10%.

Diadynamic current

mean current for **DF** mean current for **MF** 0 ÷ 40 mA
 0 ÷ 20 mA

• **MF** current during isodynamics 87,5% of the set value

Interferential current

 $\begin{array}{lll} \bullet & \text{of the set value } \mathbf{f_N} & 4000 \text{ Hz} \\ \bullet & \text{lower limit of interf. freq. } \mathbf{F_d} & (1 \div \mathbf{F_g}) \text{ Hz} \\ \bullet & \text{upper limit of interf. freq. } \mathbf{F_g} & (\mathbf{F_d} \div 200) \text{ Hz} \\ \bullet & \text{RMS current} & 0 \div 60 \text{ mA} \\ \end{array}$

<u>NOTICE:</u> If another therapy is used simultaneously with electrotherapy, the maximum current for IF4P will be reduced by 50%. There is no reduction, if the other process is lasertherapy with the point probe.

Kotz current

Parameters of the standard Kotz current

pulse time t_i
 break time t_p
 carrier frequency f_n
 pulse repetition frequency f
 polarity
 amplitude of current
 10 ms
 2500 Hz
 50 Hz
 BP (bipolar)
 0÷100 mA

Parameters of the adjustable Kotz current

• pulse time \mathbf{t}_i 1÷100 ms

• break time t_p 2÷200 ms (wherein $t_i < t_p$)

carrier frequency f_n
 polarity
 amplitude of current
 2500÷10000 Hz
 BP (bipolar)
 0÷100 mA

Waves / Electrogimnastics

pulse time T_i 0,5÷60 s
 break time T_p 1,0÷60 s

• slope % 0÷100 % (0=rectangle, 1÷99=trapezium, 100=triangle)

Medium frequency pulse current

• pulse time (modulation) **T**_i 5÷990 ms

• break time T_p 100÷4000 ms (wherein $T_i \le T_p$)

amplitude of current 0÷100 mA

TENS currents

Standard TENS current

pulse width t_i 50÷300 μs
 pulse frequency f 1÷200 Hz
 amplitude of current 0÷100 mA

HV (High Voltage)

pulse width t_i
 50÷300 μs (double pulse 50 μs distant)

pulse frequency f 1÷200 Hz

• amplitude of current 0÷100 mA (for Umax = 200 V)

TENS BURST

• pulse width t_i 50÷300 µs

batch of pulses spaced by 10ms, 20% duty factor

frequency batch of pulses
amplitude of current
0,5÷2 Hz
0÷100 mA

Träbert current

Parameters of the standard Träbert current

pulse time t_i 2 ms
 break time t_p 5 ms
 pulse repetition frequency f 143 Hz
 polarity UP (unipolar)
 amplitude of current 0÷100 mA

Parameters of the adjustable Träbert current

• pulse time t_i 1÷100 ms

• break time t_p 1÷200 ms (wherein $t_i < t_p$)

polarity
 amplitude of current
 UP (unipolar)
 0÷100 mA

Faradic current

Faradic

pulse time t_i
 break time t_p
 polarity

polarityamplitude of currentUP (unipolar)0÷100 mA

Neofaradic

pulse time t_i
 break time t_p
 2 ms
 20 ms

polarity
 amplitude of current
 UP (unipolar)
 0÷100 mA

Galvanic current

mean current 0÷50 mA

Microcurrent

amplitude of current 0÷1000 μA

CV mode

voltage amplitude 0÷100 V

CV for TENS current

voltage amplitude

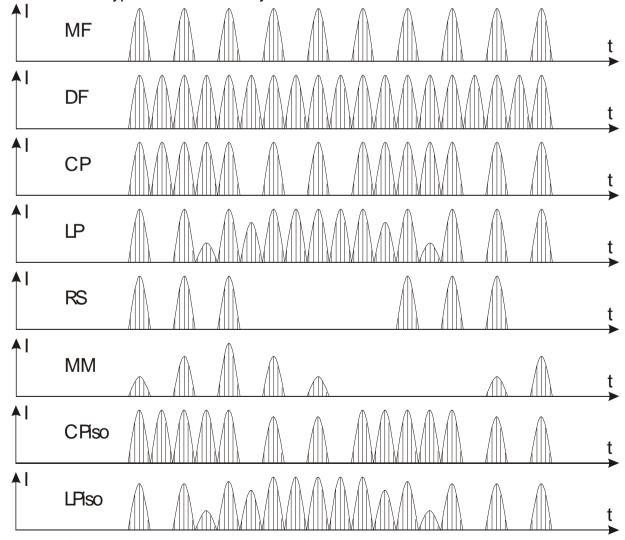
0÷140 V

II.6. Technical description – electrotherapy

II.6.1. Diadynamic currents

Medium frequency (10 kHz) amplitude modulated current with 10 ms half sinus of the following types:

- **MF** (monophasé fixé) modulation with one half of sinusoidal 50 Hz wave.
- **DF** (diphasé fixé) modulation with full wave rectified 50 Hz sinus; the **DF** modulation frequency is 100 Hz.
- **CP** (courant modulé en courtes périodes) current composed of the **DF** and **MF** waves, flowing alternately in two intervals, 1 sec. each.
- **LP** (courant modulé en longes périodes) current composed of the **DF** and **MF** waves, flowing alternately in two intervals, 6 sec. each. The **DF** and **MF** transition, and opposite, the change is smooth and takes about 1 sec.
- **RS** (rythmé syncopé) current composed of paused generation of **MF** current with equal times of pulse and break which is 1 sec.
- **MM** (monophasé modulé) current composed of MF current modulated in triangle; modulation and break times are equal (6 sec.).
- **CPiso** CP type current with isodynamics.
- **LPiso** LP type current with isodynamics.



Intensity of MF with isodynamics is 87,5% of the value set

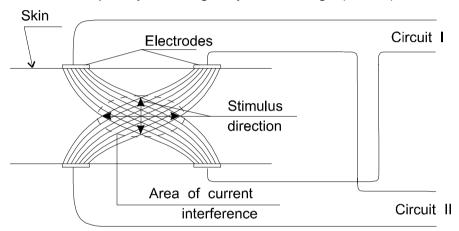
Different types of diadynamic current may be set as a sequence and generated automatically one after another.

Time of a single current type in a sequence $t = 30 \text{ s} \div 10 \text{ min}$ (step of change 30 s).

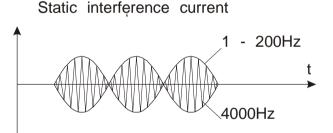
II.6.2. 4-pole interferential current

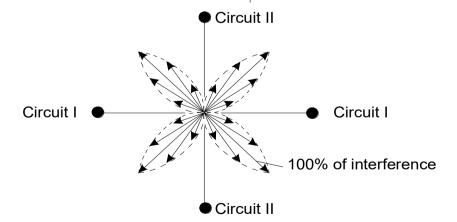
NOTICE: IF4P is used in this manual to name this type of currernt.

Interferential current generated by MULTITRONIC MT-6 is a medium frequency alternating current. This type of current occurs in patient's body as a result of interference of two medium frequency (about 4000 Hz) currents, which flow through two independent treatment circuits. They are usually applied with 4 electrodes placed in transverse circuits. The intersection of the current streams should occur close to the ill region's geometric centre. As a result of interference a therapeutic stimulus is created in the body region under treatment. The difference in frequencies of currents in each circuit creates therapeutic stimulus of frequency in biologically active range (1–200) Hz.



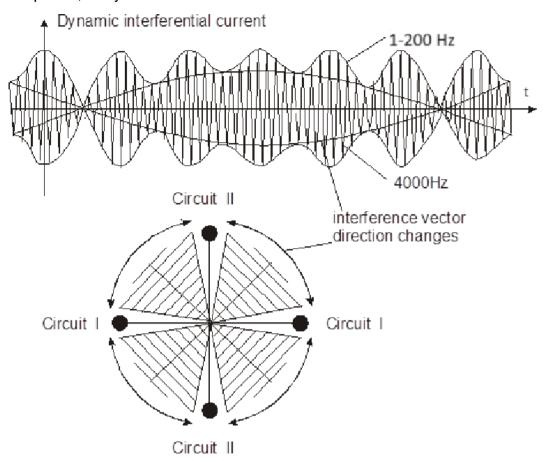
STATIC interferential current is generated when amplitudes in both channels have fixed value. Direction of action of stimulus is permanent and agrees with bisectors of angles formed by conceivable lines joining both pairs of electrodes.





Static interrupted interferential current with the same amplitude in both channels (double-channel) (4-pole / **classic interrupted**) are generated with cyclic break of modulation of static interferential current. They can be set using electrogimnastics settings.

DYNAMIC interferential current is generated when amplitudes in both treatment channels are modulated. Through introducing the currents' amplitude modulation in both channels in counter-phase, a rhythmical reversal of action of the treatment stimulus is obtained.



The advantage of the therapy with dynamic interferential current is quite even distribution of therapeutic stimulus over all the body part contained between electrodes.

ISOPLANAR interferential current is generated when two interfering amplitudes are sine modulated shifted 90 degrees in phase. In any point of surface bordered by electrodes the resulting effect may be seen as a sum of instantaneous values of both amplitudes. Depth of modulation is the same over all the body area between the electrodes. Using this type of current makes relative position of electrodes less important. Feeling of isoplanar interferential current (isoplanar vector) is soft and even over all the body area between the electrodes.

DIPOLE VECTOR is a version of isoplanar interferential current where interfering amplitudes are sine modulated in the same frequency, not shifted in phase.

The stimulus occurs only in direction of the chosen vector, which may be turned within 360° range.

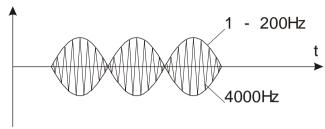
The advantage of such stimulation is that one can set the direction of stimulus after placing the electrodes.

II.6.3. 2-pole interferential current

NOTICE: IF2P is used in this manual to name this type of currernt.

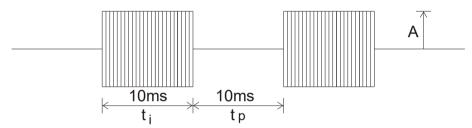
This is a static pre-modulated (single channel) interference current (2 electrode /premodulated).

The interference currents, of the IF2P type generated by the MULTITRONIC MT-6 device, are medium-frequency (4000 Hz) amplitude-modulated alternating currents.



In the screen the present frequency is shown. Change of frequency takes 15 s rise and 15 s fall.

II.6.4. Kotz current



Parameters of classic Kotz current

- ti = 10 ms [pulse time]
- tp = 10 ms [breal time]
- f = 50 Hz [frequency of pulse repetition]
- fn = 2500 Hz [carrier frequency]
- polarity BP (bipolar)
- I = 0÷100 mA [current]

Parameters of adjustable Kotz current

ti = 1÷100 ms [pulse time]
 tp = 1÷200 ms wherein ti < tp [pulse break]

• fn = 2500÷10000 Hz [carrier frequency]

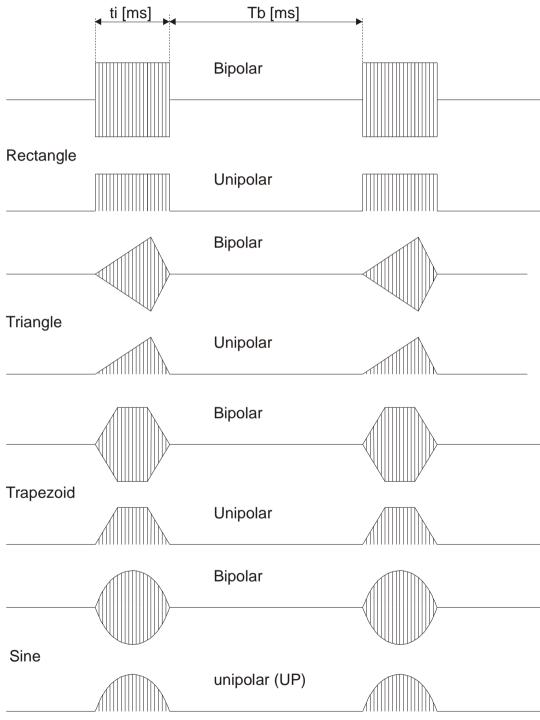
• polarity BP (bipolar)

• I = 0÷100 mA [current]

II.6.5. Medium frequency pulsed current

- current in shape of triangle, rectangle, trapezium, half sine unipolar and bipolar
- shape of the triangle envelope:
 - rise time to fall time proportion = 4:1

Modulated pulse current generated by MULTITRONIC MT-6 is medium frequency (5 kHz) pulse modulated current of shapes and parameters shown below.



Parameters

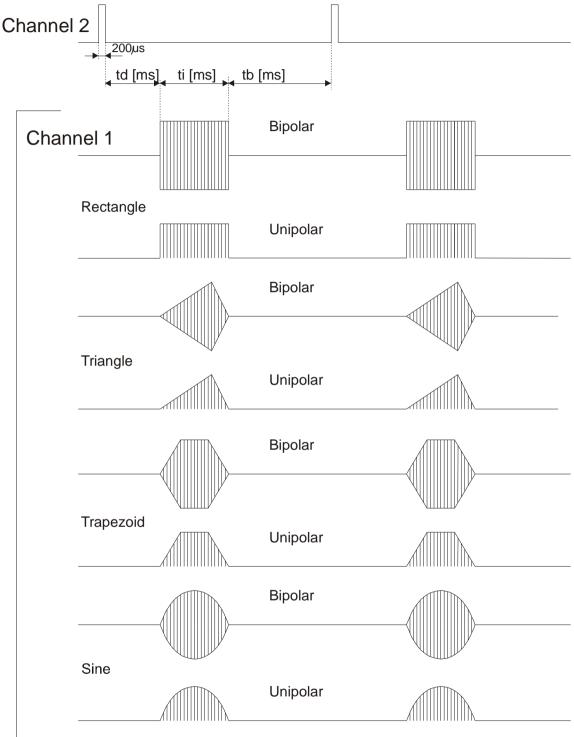
- time of modulation ti
- $5 \div 990 \text{ ms}$

break time tp

- 100 ÷ 4000 ms
- triangular modulation envelope:
 - o rise /fall time 4:1
- amplitude of current
- $0 \div 100 \text{ mA}$

II.6.6. Tonolysis

MULTITRONIC MT-6 in tonolysis mode generates rectangle pulse of 0,2 ms width in channel 2, and next, and after a delay time **td**, generates a similar pulse in channel 1. After the pause time **tp** these series of pulses are repeated. Shapes and parameters of pulses are as follows:



Parameters

- modulation time t_i 5 ÷ 990 ms
- triangular modulation envelope:
 - o rise/fall time 4:1
- delay time (chan.2.– chan.1.) t_o
- break time (chan.1.– chan.2.) tp
- amplitude of tonolysis current
- 5 ÷ 150 ms
- 100 ÷ 4000 ms
- 0 ÷ 100 mA

II.6.7. TENS current

For all TENS types:

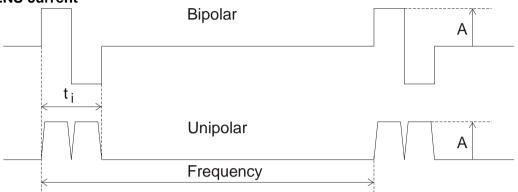
polarity unipolar or bipolar

random modulation change
 On or Off

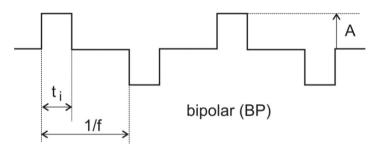
pulse width t_i 50 ÷ 300 μ s

pulse frequency f 1 ÷ 200 Hz
 amplitude of current A 0 ÷ 100 mA

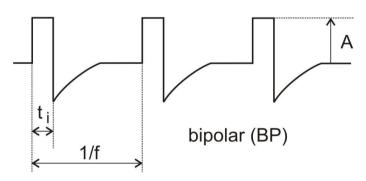
Standard TENS current



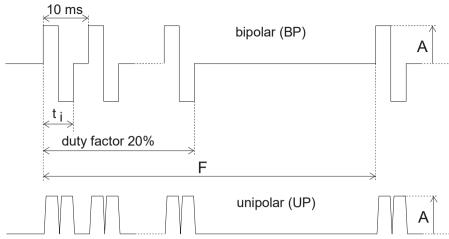
Alternating TENS current



Asymmetric TENS current



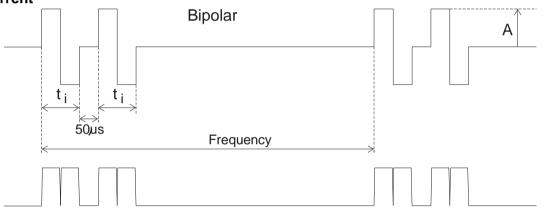
TENS BURST



• pulse width ti

- $50 \div 300 \ \mu s$
- pack of pulses (pulse every 10 ms, 20% duty factor), repeated every 0,5-2 s
- frequency pulse F
- $0.5 \div 2 \text{ Hz}$
- amplitude of current A
- 0 ÷ 100 mA

HV current

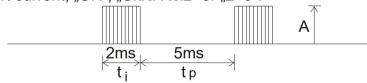


pulse width t_i

- $50 \div 300 \,\mu s$ (interval in pair of pulses is $50 \,\mu s$)
- pulse frequency f
- 1 ÷ 200 Hz
- amplitude of current A
- $0 \div 100 \text{ mA (for Umax} = 200 \text{ V)}$

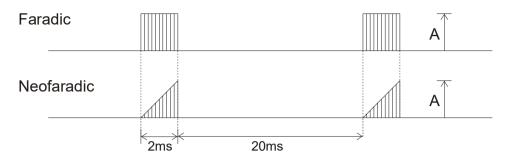
II.6.8. Träbert current

Träbert current, "UR", "Ultra Reiz" or "2-5".



- Standard:
 - o ti = 2 ms [pulse time]
 - o tp = 5 ms [pulse break]
 - o f = 143 Hz [frequency]
 - polarity UP (unipolar)
 - I = 0÷100 mA [amplitude]
- Adjustable:
 - o $ti = 1 \div 100 \text{ ms [pulse time]}$
 - o tp = 1÷200 ms [break time] wherein ti < tp
 - o polarity UP (unipolar)
 - I = 0÷100 mA [amplitude]

II.6.9. Faradic current



Faradic

- o ti = 2 ms [pulse time]
- o tp = 20 ms [pulse break]
- o polarity UP (unipolar)
- \circ i = 0÷100 mA [amplitude]

Neofaradic

- o ti = 2 ms [pulse time]
- o tp = 20 ms [pulse break]
- o polarity UP (unipolar)
- I = 0÷100 mA [amplitude]

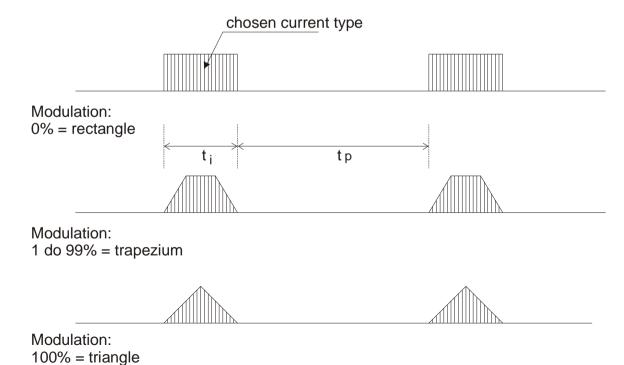
II.6.10. Galvanic current

 $I = (0 \div 50) \text{ mA [average]}$

II.6.11. Wave modulation / Electrogymnastics

Electrogymnastics can work with any type of single channel current.

The value of slope adjusted 0÷100% sets the rise and fall time of modulation. It works as follows: 0% gives a rectangle, 1÷99% gives a trapezium and 100% gives a triangle.



II.7. EMC requirements

This equipment requires special attention for EMC environment conditions and must be installed according to the information given below. The user should provide such conditions for proper functioning of the equipment.

EMC emission resistance

		Resistance test level
Subject	EMC Standard or Examination Method	Professional health care facility environment and
	or Examination Method	home health care
		environment
Port on the casing		
ESD	PN-EN 61000-4-2:2011	± 8 kV contact, ± 2; 4; 8; 15 kV by air
RF radiation	PN-EN 61000-4-3:2014	10 V/m rms before modulation) 80 MHz – 2,7 GHz, modulation: 80% AM, 1kHz
Proximity RF fields from wireless radio equipment	PN-EN 61000-4-3:2014	p. 8.10 of the Standard (Table 9)
AC. Mains Port		
Fast transients (BURST)	PN-EN 61000-4-4:2013	± 2 kV, freq. 100 kHz
SURGES	PN-EN 61000-4-5:2014	Line to line ± 0,5 kV, ± 1 kV
		Line to earth ± 0,5 kV, ± 1kV, ± 2 kV
Disturbances conducted and induced	PN-EN 61000-4-6:2014	3 V (rms before modulation)
from RF fields		0,15 – 80 MHz,
		6 V (rms before modulation) in the ISM band and in the radiofrequency bands
		0,15 and 80 MHz,
		modulation: 80% AM and 1 kHz
Voltage drops DIP	PN-EN 61000-4-11:2007	0% U _T ; 0,5 T
		in 0°, 45°, 90°, 135°, 180°, 225°, 270°,
		315°
		0% U _T ; 1 T;
		and 70% U _T ; 25 T;
		single phase 0°
Supply breaks	DN EN 04000 4 0 0040	0% U _T ; 250 T
Magnetic fields of the supply mains	PN-EN 61000-4-8:2010	30 A/m
frequency		50 Hz

^{*)} Radiation of stationary radio transmitters should not exceed the above declared levels.

Disturbances may be observed close to devices marked with the following label:



Emission levels for the professional medical care company and environment of the domestic medical care				
Subject	Applied Standard		requency bands MHz	
Harmonics of current	PN-EN 61000-3-2:2014	The device meets the requirement small power does nod require any	ents of the Standard and due to restings.	
Fluctuations of voltage and light flickering	PN-EN 61000-3-3:2013	·	The device meets the requirements of the Standard and due to small power does nod require any testings.	
_		66 dBµV (quasipeak.) 56 dBµV (avr.)	0,15 - 0,5	
Conducted RF emission	PN-EN 55011:2016 Group 1, Class B	56 dBµV (quasipeak.) 46 dBµV (avr.)	0,5 - 5	
		60 dBμV (quasipeak.) 50 dBμV (avr.)	5 - 30	
Radiated	PN-EN 55011:2016	Elecrical field a	nt 10 m distance	
RF emission	Group 1, Class B	30 dBμV/m (quasipeak.)	30-230	
IXI GIIII33IUII	Gloup 1, Glass B	37 dBµV/m (quasipeak.)	230-1000	

Cables used with the device:

- cables connecting the ultrasound head to the device up to 2 m
- cables connecting the laser probes to the device up to 2,5 m
- cables connecting the electrodes to the device up to 2,5 m
- mains cable up to 1,8 m

IMPORTANT: Using cables exceeding the limits may cause increased emission or lower resistance of the device.

<u>IMPORTANT:</u> Telecommunication equipment using radio frequencies may affect operation of this device.

Working environment: Health care facilities and domestic medical care environments.

II.8. Storage and transportation conditions

The device with accessories should be stored in the original packaging observing the following conditions:

• ambient temperature 5°C ÷ 40°C

relative humidity up to 85% condensation-free

• atmospheric pressure 780-1060 hPa

The device with accessories should be transported in the original packaging observing the following conditions:

• ambient temperature -10°C ÷ 45°C

relative humidity
 up to 95% condensation-free

atmospheric pressure 780-1060 hPa

NOTICE: Do not expose the device or accessories to outdoor weather conditions.

III. ACCESSORIES

III.1. Equipment supplied with the device

•	E–S 50 silicone flat electrode with P-50 sponge cover	4 pcs
•	E-A 75 aluminium flat electrode with P-75 sponge cover	4 pcs
•	K-2L cable for 2 electrodes	2 pcs
•	OR-1 elastic strap, dimensions (50x500) (mm)	2 pcs
•	OR-2 elastic strap, dimensions (50x800) (mm)	2 pcs
•	mains cable	1 pcs
•	T-0,315AL, 250V fuse	2 pcs
•	instructions for use	1 pcs
•	warning signs for use on doors	1 set

gel for ultrasound treatments
 0.5L (if an ultrasound head is ordered a the device)

III.2. Basic accessories

Basic accessories - laser:

• Laser probes (applicators)

S–1N : point probe	50 mW / IR	[pulse mode]
S-2N: point probe	40 mW / R	[continuous and modulated mode, adj. power]
S-2B: point probe	80 mW / R	[continuous and modulated mode, adj. power]
S-3N: point probe	400 mW / IR	[continuous and modulated mode, adj. power]
SP–1B : cluster probe	720 mW / R	[continuous and modulated mode, adj. power]
SP–2B : cluster probe	1040 mW / R + IR	[continuous and modulated mode, adj. power]
SP–3 : cluster probe	1440 mW / IR	[continuous and modulated mode, adj. power]

Basic accessories – ultrasound:

Ultrasonic applicator (head) 1,3 cm²:
 Ultrasonic applicator (head) 5 cm²:
 Ultrasonic applicator (head) 6x3 cm²:
 SU-5
 SUP-6

Basic accessoriest – electrotherapy:

- E-P or E-P2 point electrode (with ball shaped and flat ends exchangeable)
- flat aluminium electrodes of different sizes E-A5, E-A10, E-A15, E-A50, E-A75, E-A100, E-A125
- flat electrodes of ...N type with plug connection instead of a socket (E-A5N, E-A10N, E-A15N, E-A50N, E-A75N, E-A100N, E-A125N)
- silicone electrodes E-S50, E-S75
- sponge covers of different sizes P-5, P-10, P-50, P-75, P-100, P-125, P-8M, P-8D, P-18, P-36
- velcro fixing straps O-R1, O-R2, O-R3
- velcro fixing straps of double width O-R1S, O-R2S, O-R3S
- · 2-electrode treatment cable with plug instead of a socket K-2LN
- 2-electrode treatment cable with polarization switch K-2LW
- cable for special electrodes K–J
- K-R or K-RN branching cable for connecting double number of electrodes

WARNING: If a laser applicator will be used with the device, protective equipment for the patient and the operators (eyewear) is necessary.

<u>WARNING:</u> The manufacturer does not take any responsibility for using with MULTITRONIC MT-6 accessories other than those of EiE. It is acceptable to use the equipment having a certificate of compatibility with the EiE requirements.

<u>WARNING:</u> Regular control of electrodes is obligatory. Do not use electrodes with excessive resistance.

IMPORTANT: Regular control of connecting cables is recommended.

III.3. Connecting the device with accessories

The control device allows you to perform the treatments of individual therapies with the appropriate equipment. Without accessories, the device is not applicable.

At least one laser applicator is needed for laser therapy treatments.

For ultrasound treatments, at least one ultrasound applicator is needed.

At least one pair of electrodes is needed for electrotherapy treatments.

The accessories connected for each therapy do not affect in any way the other therapies with the note below.

IV. PREPARING OF THE DEVICE FOR USE

WARNING: Thoroughly read the instructions for use before using the device.

- 1. If the device was for some time in temperature below 0°C (e.g. in transport) it should be unpacked and left in room temperature for about 4-8 hours. Only then it can be plugged into mains and switched on.
- 2. The device should be placed in such a place that connected cables (especially the mains cables) are not exposed to pulling or tearing by persons passing by. Such a situation may expose people to an electric shock and the equipment to damage or destruction.
- 3. It is recommended to remove the protective sticker from the display. Gently lever up the sticker with your nail and remove it. Leaving the sticker on may impair the vision of the display.

IMPORTANT: Viscose pads should be washed out with running water before first use. Washing is necessary to remove the agent softening the viscose for storage and transport.

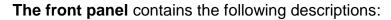
<u>IMPORTANT:</u> The ultrasound heads are calibrated and dedicated to an individual device. Using an non-calibrated ultrasound probe can result in using inaccurate parameters, which may lead to usage of too high power. Please contact the manufacturer for calibration of the ultrasound probe (for example coming from another device or newly bought).

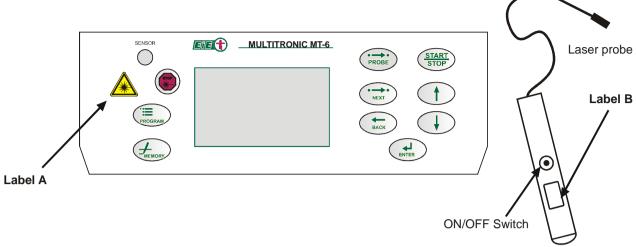
IV.1. Labels' placement

If laser treatment is performed, the door to the treatment room should be labelled as follows (signs are included as accessory):



WARNING - VISIBLE AND INVISIBLE LASER RADIATION PROTECT EYES FROM DIRECT AND DISSIPATED RADIATION





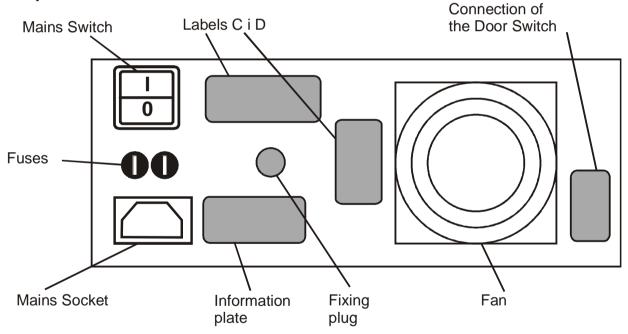
Label A – on the front panel

Label B - on the laser probe; shows output end of the probe - the one where laser beam goes out.





Back panel:





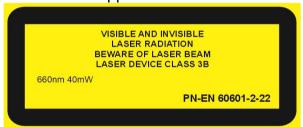
Labels C i D – on the back panel



Information labels for laser applicators For the laser applicator S-1N:



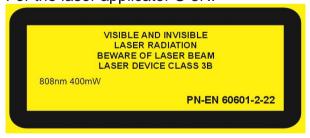
For the laser applicator S-2N:



For the laser applicator S-2B:



For the laser applicator S-3N:



Ulanudoeparides ultanudepry/ME/33ME cofrensachkeloe pledepry/0180± cltylato/5100/o PNE-68801.25

For the laser applicator SP-1B:



For the laser applicator SP-2B:



For the laser applicator SP-3:



IV.2. Recommended workplace organization

The control unit should be positioned firmly in the workplace before treatment: on a table, desk or trolley, near the mains socket ~230 V 10% 50 Hz. The device should be placed at a suitable height which allows easy manipulation of controls on the front panel. Sunlight, or other bright light may dim the screen and decrease LEDs visibility, so the front panel should not be lit with direct light.

It is recommended that the workplace organization allow for easy and uninterrupted access to all controls and accessories. Special care must be taken to put the mains and connecting cables aside from the area where people move as this may cause accidental stumbles or pulling of the cable. Between treatments, the cables should be put aside

safely not to be pressed or broken by a drawer or cabinet doors. Laser and ultrasound probes should be put aside on a holder when not in use, this protects them from mechanical damage.

NOTICE: In particular, care should be taken to ensure easy access to the power switch (on the rear panel of the device).

IV.3. Connection of cables and treatment applicators

The cables for treatment ought to be connected to appropriate sockets:

- Yellow– Laser applicators
- Grey Electrotherapy cables
- Blue Ultrasound heads

For ease of use the plugs and sockets have the same colours respectively.

<u>IMPORTANT:</u> Connection and disconnection of electrotherapy cables must only be done when the device is switched off. Otherwise the patient may experience an unpleasant electrical shock.

IMPORTANT: Plug has an automatic lock protecting it from falling off from the socket (when connecting one should hear a "click"). The plug fits the socket only in the position with the arrow symbol up. When disconnecting, one should gently pull the plug out, but strong enough to unlock it, avoiding to turn the plug around while in the socket. When disconnecting, the plug should be held near the socket, avoid pulling the plug by the cable, otherwise the cable may be broken.

NOTICE: For ionophoresis, metal electrode should be used as the active one (the one with the medicine).

NOTICE: For unipolar and DC (galvanic) current: anode (plus) should be connected to the red cable's end and cathode (minus) to the black end.

IV.4. Switching on

WARNING: Do not switch on and off the device when electrodes are put on the patient. This may cause the patient to receive unpleasant electric shock.

IMPORTANT: Before switching on the POWER button connect treatment probes to the sockets in front of the device.

IMPORTANT: This device is manufactured with the insulation of the first class. Connect the device to the socket with grounding pin.

The device is turned on by the POWER button on the back panel into position "I".

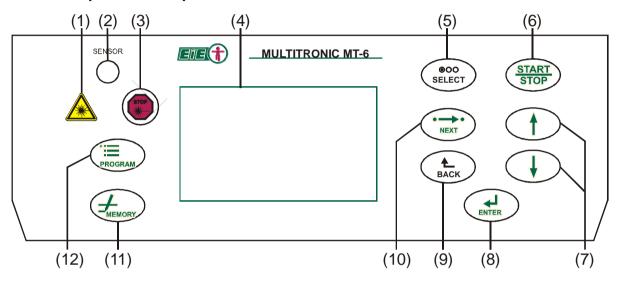
V. OPERATION AND HANDLING OF THE DEVICE

<u>WARNING:</u> All treatments using MULTITRONIC MT-6 should be performed carefully by a qualified physiotherapy technician. Otherwise, the therapeutic effects may be limited and the patient and staff may be exposed to health risks.

NOTICE: A number in parentheses, ex. (10) used in the test refers to a corresponding number on the front panel in the drawing in part V.1. "Front panel description".

NOTICE: In this chapter, if the character "+" accompanies a button icon, it means that two respective buttons should be pressed simultaneously.

V.1. Front panel description



No.	Symbol	Description		
1		Warning label		
2		Sensor for laser power measurem	nent	
3	STOP	Emergency energy turn OFF		
4		Colour LCD screen with touch par	nel	
5	●○○ SELECT	Change of the type of therapy		
6	START STOP	Turn ON / OFF the treatment		
7		Parameter value cotting	Increase value of the parameter	
		Parameter value setting	Decrease value of the parameter	
8	ENTER	Accept the choice		
9	BACK	Move to menu for additional functions or return to the previous screen		
10	●→● NEXT	Go to next item on the screen		
11	MEMORY	Individual sets of parameters saved by the user		
12	PROGRAM PROGRAM	Pre-programmed parameter sets for various treatments		

V.2. Preparation for treatment

V.2.1. Connection of applicators

 Before turning on the device, therapeutic probes and cables should be connected as described in IV.3. "Connection of cables and treatment applicators"

V.2.2. Switching on

WARNING: All treatments using MULTITRONIC MT-6 should be performed carefully by a qualified physiotherapy technician. Otherwise, the therapeutic effects may be limited and the patient and staff may be exposed to health risks.

WARNING: In the case of abnormal functioning of the device, which may result in danger to the operator or patient, stop the treatment immediately and proceed as in chapter VI. "Maintenance".

IMPORTANT: Before switching on check the condition of the cables. If they are damaged, call for a qualified maintenance technician to repair them.

IMPORTANT: This device is manufactured with the insulation of class I. Connect the mains supply cable to the socket at the back of the device, and plug the cable into the wall socket with a grounding pin.

NOTICE: Do not bend the cables at acute angles and do not wind them up tight, because they can be damaged.

Electrotherapy treatments

WARNING: Do not switch on or off the device when electrodes are put on the patient. This may cause the patient to receive unpleasant electric shock.

Lasertherapy treatments

<u>WARNING:</u> Before turning on the device, both the patient and the staff must put on protective eyewear. Otherwise the laser light can damage the eyes.

WARNING: To safeguard against turning on the laser by unauthorised persons, turn off the power if the laser is not used. Turning it back on will require gentering the protective password.

Ultrasound treatments

<u>WARNING:</u> The ultrasound heads are calibrated and dedicated to the individual device and should only be used with the device they were calibrated for. Do not use the heads that are not calibrated with a given device, instead send them to the manufacturer for calibration. The heads without proper calibration may not work properly or may show inaccurate parameters.

When switching on, observe the following sequence:

- connect the applicators and/or electrodes
- put protective laser eyewear on if lasertherapy is to be performed (both the patient and the staff)
- connect the device to the mains power supply
- turn on the power button on back panel

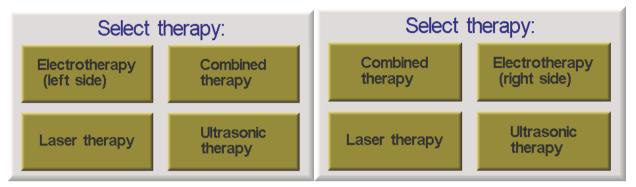


V.3. Information presented by the device

V.3.1. Choice of therapy

This can be done as follows:

- either press the LCD screen with your finger in the area of desired applicator (treatment clock) - the device will show the treatment parameters for the selected channel.
- ●00 or press the button selection screen will appear (respectively for the left and right channel):



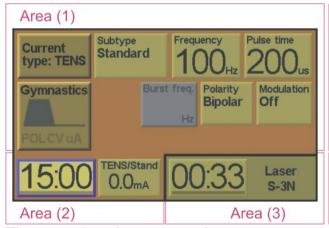
The choice is confirmed by touching the appropriate item on the screen. It is possible to withdraw pressing "Close".

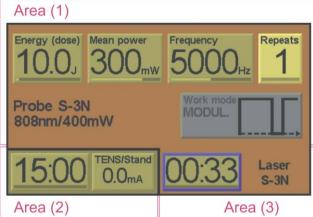
The chosen therapy is marked with a blue frame, and in the field (1) relevant parameters are displayed.

NOTICE: Switching over between applicators can take about 1 s. Wait until the device has switched over to the chosen applicator.

V.3.2. Main screen

After turning on the device the screen for editing treatment parameters shows up. Fields that cannot be changed are coloured in grey.





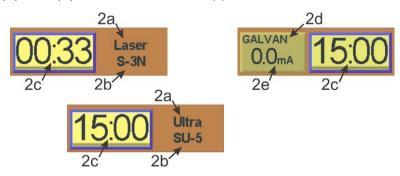
There are 3 main areas on the screen:

- (1) parameters area
- (2) applicator 1 area (here electrotherapy)
- (3) applicator 2 area (here laser)

In areas (2) and (3) the times of treatment and the type of detected applicator, or the kind of the selected current are displayed. When there is no probe in a channel, the sign "-----" is displayed. The probe chosen for edition / current is indicated by blue frame around timer. Treatment parameters are displayed in area (1).

V.3.3. Applicator areas

Areas (2) and (3) are connected to applicators' related sockets.



There are the following fields in these areas:

(2a): related applicator symbol

"Laser" – laser socket

"Ultra" – ultrasound socket

(2b): type or lack of applicator / current or if the current is missing

for lasertherapy: "S-1N", "S-2N", "S-2B", "S-3N", "SP-1B", "SP-2B", "SP-3", "---" for ultrasound therapy: "SU-1", "SU-5", "SUP-6", "-----"

(2c): time of treatment for a given applicator

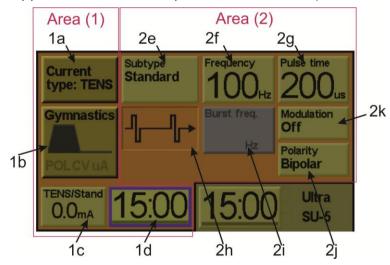
Additionally for electrotherapy

(2d): type of chosen curren ("DD", "IF", "STIM", "TENS", "KOTZ", "UR", "Farad", "GALVAN") with sub-type (if applicable)

(2e): current value set

V.3.4. Parameter screen - electrotherapy

Appearance of current parameters screen (in the example TENS):



There are following fields:

Area 1 (constant)

(1a): parameter: current type

(1b): additional options: wave/electrogymnastics, CV mode, polarity, microcurrent, combined therapy

(1c): parameter: treatment time

(1d): parameter: current [mA]

Area 2 (changeable – depends on current type, here TENS)

(2e): parameter: sub-type of current (if applicable)

(2f): parameter: frequency

(2g): parametr: pulse time

(2h): parametr: irritating modulation (stochastic change) - On /Off

(2i): parametr: polarity

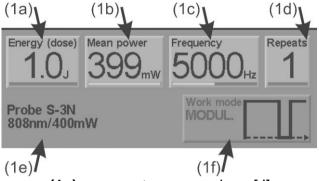
(2i): parametr: pulse batch repetition frequency

(2k): pulse shape visualisation

V.3.5. Parameter screen – lasertherapy

Laser point probes

Screen of a point probe:



(1a): parametr: energy dose [J]

(1b): parametr: mean power [mW]

(1c): parametr: modulation frequency (for modulation mode) or pulse frequency (for pulse mode)

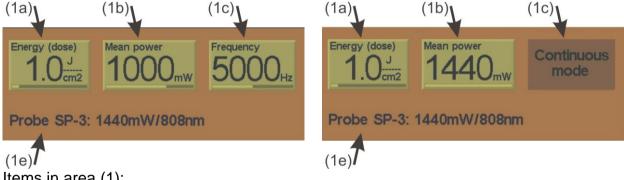
(1d): parametr: number of repetitions

(1e): description of the connected probe

(1f): probe work mode (continuous / modulated / pulse)

Laser cluster probes - one-wavelength

Screen of laser cluster probe (one-wavelength) (SP-1B, SP-3):



Items in area (1):

(1a): parametr: energy density [J/cm²] (1b): parametr: mean power [mW]

(1c): parametr:

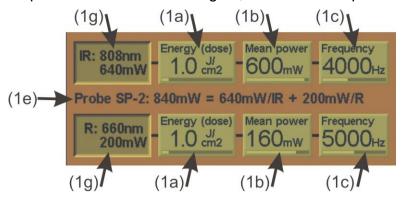
modulation frequency (for modulated mode)

work mode type (for continuous mode)

(1e): description of the connected applicator

Laser cluster probes - double-wavelength

It operates with two wavelengths, so the SP-2B probe has a different parameter screen:



Items in area (1):

(1a): parametr: energy dose [J/cm²] (1b): parametr: mean power [mW]

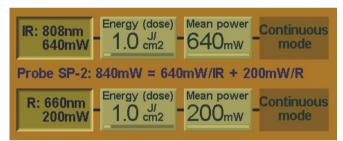
(1c): parametr:

- modulation frequency (for modulated mode)
- work mode type (for continuous mode)

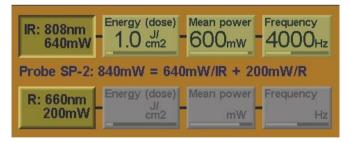
(1e): description of connected applicator

(1g): emission on / off for chosen laser wavelength in SP-2B

This same screen is for the continuous work mode (maximum power):

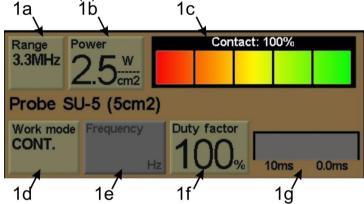


Single wavelength turned off:



V.3.6. Parameter screen - ultrasound

View of the area (2) of the screen:



There are following fields:

(1a): parameter: ultrasound frequency [MHz]

(1b): parameter: power density [W/cm²]

- for continuous work mode it is peak value and mean value at the same time
- for impulse work mode it is peak value
 Mean value is the product (ratio) of peak value and duty factor

(1c): graphic representation of the degree of treatment head contact with the patient's body

(1d): parameter: work mode (continuous / pulsed)

(1e): parameter: pulse frequency (for pulsed mode)

(1f): parameter: duty factor for pulsed mode [ratio: duration of pulse to the repetition period]

(1g): graphic representation of pulsed mode [first number is the pulse time, second the break time]

V.3.7. Selection of parameter

We can choose a parameter in one of the two ways:

- pressing with a finger on the LCD in the field of the desired parameter
- repeatedly pressing NEXT, which consecutively selects parameters.

The parameter chosen for edition is marked by pulsating brightness.

V.3.8. Changing the parameter value

Regulation (change of value) is done only with buttons and on the keyboard. Longer pressing of any of the two keys gives a fast change. In some parameter numeric fields there is a strap at the bottom showing the presently chosen value compared to its limits.

V.4. Performing treatments – electrotherapy

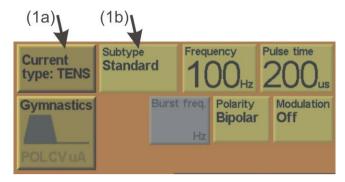
V.4.1. Ranges of treatment parameters' setting

Treatment parameters may be regulated in ranges shown in chapter II.6. "Technical data – electrotherapy".

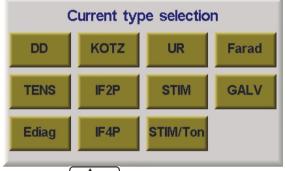
Time of treatment may be set at between: 30 s ÷ 99 min.

V.4.2. Choosing current type

The current type for treatment may be chosen by touching field (1a) on parameters screen:



Screen for the left channel:



Pressing Cancels the choice.

Screen for the right hand channel:



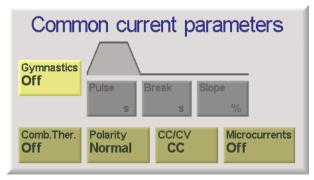
If sub-types are accessible for a chosen current, one may chose them by touching the field (1b), and with the buttons and one selects the desired sub-type.

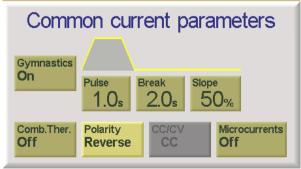
V.4.3. Choosing wave modulation / electrogymnastics

In order to choose wave modulation touch field (1b) in the parameter screen:

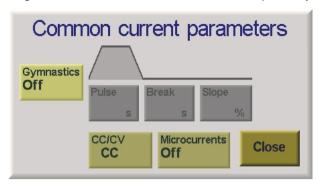


Then this screen appears:





Right hand channel has neither the polarity field, nor the field of combined therapy:



In the screen one may toggle the field "Gymnastics" to On / Off.

Modulation parameters may be chosen by touching the field on the screen or with the key on the keyboard.

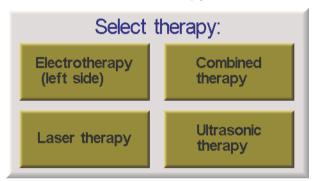
V.4.4. Combined therapy

Combined therapy (electrotherapy with ultrasound) can be switched on in one of the two ways.

NOTICE: During this therapy the current flows only in the left electrotherapy channel.

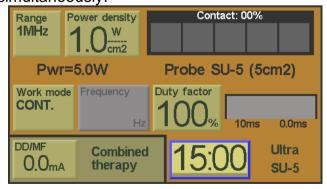
A. When choosing the therapy

Chose the field "Combined therapy".



- The treatment parameters are set separately for ultrasound therapy and for electrotherapy.
- In this case the timer is just one the same for both therapies.
- The treatment starts when one presses START/STOP or increases the current.
- Both the ultrasound and the current start simultaneously.





B. On the screen of electrotherapy

To choose the combined therapy one should choose ultrasound therapy in one parameter window and the electrotherapy parameters in the other. Then press the button 1b in the area of electrotherapy parameters (as V.4.3. "Choosing wave modulation / electrogymnastics"). Then with the key "CombTher" toggle the combined therapy ON/OFF.

"TS" will be highlighted on the electrotherapy parameters screen.



Continue as in option A, with a note as follows.

NOTICE: If the combined therapy is chosen, there are two clocks on the electrotherapy screen to be set (separately for each therapy). When the ultrasound time is over the electrotherapy can be still active, up to its selected time, but the ultrasounds are not generated. This way the whole treatment time can be longer than in the case of simultaneous version (as above in point A), which is shorter.

IMPORTANT: The passive electrode in electrotherapy is with the red end, the active electrode is the surface of the ultrasound head. The black end is not used.

V.4.5. Setting the parameters

The electrotherapy parameters are set as described in V.3.8. "Selection of parameter" and V.3.9. "Changing the parameter value".

V.4.6. Setting currents (CC mode)

Timer country currents (come as)
Intensity of current is chosen for setting by touching the field next to treatment timer. Using
and on the keyboard one may set intensity.
Increments of change depend on the present value and are as follows:
up to 2 mA: 0,1 mA
up to 5 mA: 0,2 mA
up to 10 mA: 0,5 mA

Quick pressing of the button changes intensity double fold, i.e.:

2 mA

up to 2 mA: 0,2mA up to 5 mA: 0,4 mA up to 10 mA: 1 mA up to 20 mA: 2 mA >20 mA: 4 mA

up to 20 mA: 1 mA

>20 mA:

V.4.6.1 Microcurrents

Can be activated with any kind of current, apart from tonolysis and 4-pole interferential (IF4P). The increment of current depends on present value and is as follows:

up to 200 μ A: 10 μ A above 200 μ A: 20 μ A

NOTICE: For microcurrents:

- The CV mode is inactive.
- Choosing double-channel current (tonolysis, IF4P) turns off microcurrents.

NOTICE: Maximum intensity of microcurrent is 1000 μ A, but it is shown on the screen as 999 μ A.

V.4.7. CV mode

CV mode may be set for all currents apart from: microcurrents, tonolysis and 4-pole interferential current (IF4P).

The voltage may be changed by touching the field next to the treatment timer. Using and on the keyboard one may set voltage.

The increment depends on the present value and is as follows:

up to 20 V: 1 V up to 50 V: 2 V above 50 V: 5 V

Quick pressing of the button changes the increment double fold, i.e.:

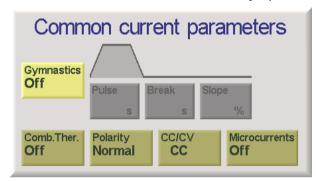
up to 20 V: 2 V up to 50 V: 4 V above 50 V: 10 V

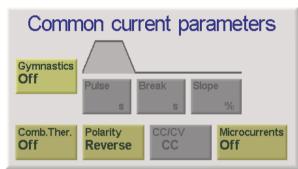
NOTICE: For CV mode:

- You cannot set microcurrents.
- You cannot set "reverse" polarity.
- Choosing double-channel currents (tonolysis, IF4P) turns off the CV mode.

V.4.8. V.4.8. Change of current direction (polarity)

For changing current direction between electrodes (polarity) touch field 1b ("Gymnastics") on the parameter screen (see V.4.3. "Choosing wave modulation/electrogymnastics") Next set direction in the field "Polarity" ("Normal" or "Reverse").





NOTICE: "Normal" polarity means current flows in direction from electrode connected to the red end of a cable to black end of a cable. "Reverse" polarity means the opposite direction.

<u>IMPORTANT:</u> Chosen polarity is not remembered after turning the device off. On the next starting the device polarity is always set to "Normal".

NOTICE: Polarity may be changed only in the left hand channel.

NOTICE: Polarity cannot be changed for double-channel current (tonolysis, IF4P).

NOTICE: If polarity is set to "reverse" it is impossible to choose CV mode.

V.4.9. Starting treatment

The electrotherapy treatment starts if START/STOP has been pressed on the keyboard and the current increased. Also increasing the current alone will start the process.

V.4.10. Temporary pause of treatment (pause)

Treatment may be interrupted by pressing START/STOP on the keyboard.

When pausing the current decreases in a controlled manner at the rate of 20 mA/s.

The treatment may be restarted by increasing the current.

V.4.11. Termination of treatment

Treatment ends in one of the following cases:

- time of treatment runs out
- treatment was stopped by the user

NOTICE: After the end of treatment the current decreases gradually in order to ease the feeling of patient. Depending on the used value of current this may take up to 5 s.

V.4.12. Circuit break detection

The patient current is continually monitored. If a significant current value drop (in comparison to the set value) is detected, it triggers an acoustic alarm of a modulated sound. The device than decreases the current to 0 mA and tries to resume the operation smoothly.

V.5. Performing treatments – lasertherapy

V.5.1. Ranges of parameters

- The following parameter ranges are specified in II.3 "Technical data laser"
 - mean power
 - frequency
- For point probes is possible to set:

dose 0,1 ÷ 200 J
 time 1 s ÷ 99 min.

number of repetitions of dose 1 ÷ 99

• For cluster probes is possible to set:

dose
 time
 0,1 ÷ 10,0 J/cm²
 1 s ÷ 99 min.

V.5.1.1 "Two colour" probe SP-2B

In this probe it is possible to switch ON and OFF diodes of a chosen wavelength. It can be done by touching the field (1g) (see V.3.5. "Treatment parameters screen – lasertherapy" above) on the screen. The displays of inactive wavelength will be greyed.

V.5.2. Mutual recalculation of lasertherapy parameters

Change of one parameter results in recalculating other parameters in the following way:

- change of energy dose recalculates the time of treatment
- change of power recalculates the time of treatment (and frequency in case of S-1N applicator)
- change of number of repetitions recalculates the time of treatment
- change of frequency in case of S-1N applicator recalculates the time of treatment and power
- change of time recalculates the power (only for point probes)
- if recalculated parameter would go off its range, the change is not possible

V.5.3. Increments of change of parameters

The point probes

Mean power regulation in the whole range: increment is 1 mW.

Time regulation: increment is 1 s

Energy dose regulation: increment is 0,1 J Frequency regulation: increment is 10 Hz

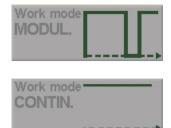
Cluster probes

Mean power regulation in the whole range: increment is 10 mW.

Energy dose regulation: increment is 0,1 J/cm² Frequency regulation: increment is 10 Hz

V.5.4. Work modes

The work mode of laser applicators depend on the type of applicator and chosen power.



Modulated work mode – the applicator radiaties laser light in pulses at the set frequency and the pulse width depending on mean power (available in applicators S-2N, S-2B, S-3N, SP-1B, SP-2B, SP-3)

Continuous work mode - the applicator radiaties laser light without breaks with maximum available power (available in applicators S-2N, S-2B, S-3N, SP-1B, SP-2B, SP-3)



Pulse work mode - the applicator radiaties laser light in short pulses of high power with given frequency (available in applicator S-1N)

V.5.5. Starting treatment

Chose the applicator with SELECT or touching the field on the screen.

NOTICE: Switching over from any applicator to another may take up to

NOTICE: Switching over from one applicator to another may take up to 1 second. You have to wait until the applicator is changed.

- To switch the probe in the "ready" mode (ready for emission) press start signal starts (if it was activated in the menu of additional functions).
- The description of the applicator type changes colour to white. Progress bar under timer shows time left till the end of treatment. The background colour of timer is:
 - o Yellow when in the ready mode or the emission mode
 - Green after end of treatment (when the whole dose has been emitted)
- Typing down password may be required as described in V.5.6 "Lasertherapy access code (password)" below.
- For starting treatment point the applicator output side to the treatment area on the patient and press the button on the applicator once. Emission starts, which is signalled with a sound and by the blue light on the applicator.

During treatment the time left till the end of treatment is shown on the screen. If repetitions of dose were set, the time shown on timer is the time till the end of a single dose (one repetition) and the number of remining repetitions is shown on the screen.

NOTICE: During the lasertherapy treatment it is not possible to change parameters.

NOTICE: If the treatment is not started within one minute after starting the readiness mode, for safety reason the "ready for emission" mode is stopped. The following information appears:

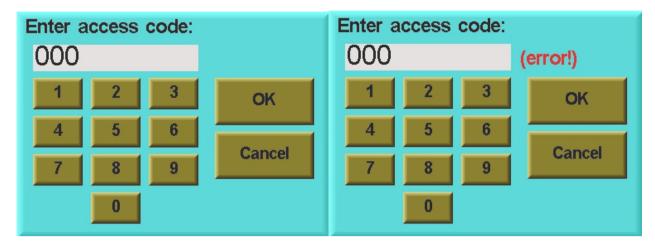


V.5.6. Lasertherapy access code (password)

NOTICE: Access code protects laser from being used by unauthorised persons.

In order to start readiness mode (laser ready for emission) press stop. If this is the first laser applicator activation after turning on the device (or the laser treatment has not been

performed for 60 minutes), the device asks for the access code. The access code is 3 last digits of the device serial number (**SN**) which is printed on the label on the back of the unit.



If a wrong code is typed, a message "error!" is displayed on the screen in red. You have to type the code again.

V.5.7. Temporary pause during laser treatment (pause)

During treatment you can stop emission by pushing the button on the applicator once. The next pushing of the button continues treatment.

If the treatment is stopped and not continued within one minute, the ready for emission mode is stopped and information is shown as in p. V.10. "Information given by the unit during work".

V.5.8. Termination of treatment

Treatment ends up in one of following cases:

- The time of treatment elapses signal "ready for emission" on the probe stops, the timer background turns green; sound signal starts, which may be stopped by pushing any button.
- When the emergency stop button is pressed. emission is immediately stopped and ready for emission signal stops

NOTICE: When emergency stop was used, in order to continue treatments you have to turn the device off and on again. Pressing the emergency button stops all treatments.



- Pressing the button
- Malfunction was detected in the device or in the applicator treatment is stopped automatically (possible options are described in p. V.10 "Information given by the unit during work").



In the case of emergency end of treatment, the related information appears on the screen and will be displayed until OK is pressed. Necessary actions should be taken to remove the malfunction, depending on the kind of it. Assistance of a qualified maintenance technician may be required.

V.5.9. Treatment with repetitions

In the case of laser treatments where more than one point has to be consecutively radiated, MULTITRONIC MT-6 has special function for setting the number of doses repeated. You can set from 1 to 99 repetitions of dose with the same parameters.

When more than 1 repetition is set, after the end of dose in a particular place, emission stops and a signal is produced. Than you have to move applicator to the next area on the patient and push the button on the applicator. The emission of the next dose starts.

NOTICE: For safety reasons the number of repetitions is reset to 1 after the full cycle has been emitted. You have to set it again in every treatment.

NOTICE: During emission the device displays the time left till the end of single energy dose repetition.

NOTICE: Setting the repetition number is possible only for the point probes.

V.5.10. Types of laser irradiation

V.5.10.1 Irradiation of point

- use a point applicator
- keep the applicator no higher than 2 cm above the irradiated area

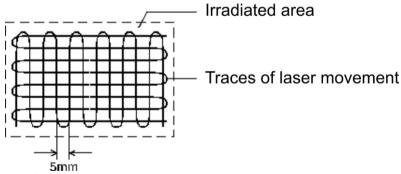
V.5.10.2 Irradiation along the line

- use a point applicator
- move the applicator evenly along the line, no higher than 2 cm above the treated area, at a speed of 2 cm per second, changing direction when end of line is reached

V.5.10.3 Irradiation of surface with a point applicator

NOTICE: For irradiation of big surfaces we advise to use the multi-diode ("cluster") probes.

During surface irradiation with a point applicator move the applicator no higher than 2 cm over the treated area, at 2 cm per second. Move along the parallel lines spaced by 5 mm, changing direction at the end of line. Then change direction perpendicularly and start moving along parallel lines. The method of movement is shown here:



NOTICE: For surface irradiation treatments we optionally suggest the use of cluster ("shower") laser applicators.

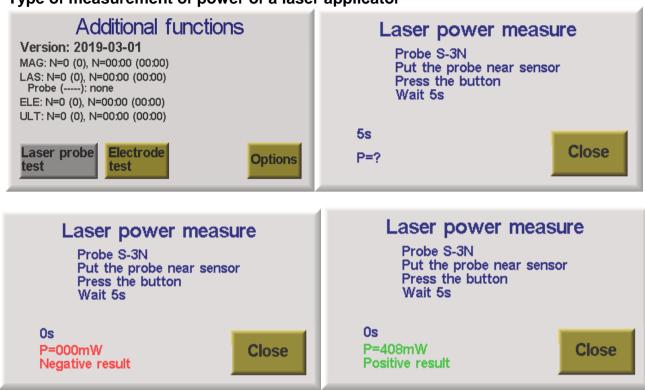
V.5.11. Measurement of power of a laser probe

WARNING: During treatments, the operator and patient must wear eye protection. Otherwise the eye vision can be damaged.

The device has the following functions for assuring proper work of laser applicators:

- During laser emission the feedback signal from laser diode is checked. When deviation is higher than +/- 20% of the nominal, the malfunction of applicator is signalled.
- The device is equipped with a power measurement sensor on the front panel, which can be used in the way described below.

Type of measurement of power of a laser applicator



- In order to start the power measurement, first chose the proper applicator and press

 In order to start the power measurement, first chose the proper applicator and press

 BACK

 Additional functions will appear. Chose "Laser probe test".
- The button on the applicator will light up showing ready for emission mode. Press the probe to the sensor (white circle in the upper left corner of the keyboard) and press the button on the applicator. The emission and measurement of power starts and continues for 5 seconds.
- During the test pay attention to hold the applicator's end tightly to the sensor. It should be positioned at (90°) to the sensor. Inaccuracy of the angle usually underrates the readout.
- When the measurement comes to an end, the value measured (in mW) is displayed on the screen. The value should not deviate more than +/-20% from the nominal value of a given applicator. In other case, the test should be repeated with careful attention to tight and proper holding of the applicator to the sensor. If several tests do not give the proper value, contact the manufacturer or authorised service.
- The value measured stays on the screen until "Close" is pressed and then the device automatically returns to the main screen.

V.6. Performing treatments – ultrasound therapy

V.6.1. Ranges of parameters

The following parameter ranges can be set as specified in II.4 "Technical specification – ultrasound"

- acoustic frequency
- power density

- work mode (continuous /pulsed)
- pulse frequency (for pulse mode only)
- duty factor (for pulse mode only)
- treatment time 30 s ÷ 30 min.

NOTICE: The power density for the modulated mode is limited to the value of maximum continuous power density (see .II.4 "Technical specification – ultrasound").

V.6.2. Increments of change of parametrs

Power: one step is 0,1 W/cm² Treatment time: one step is 30 s Pulse frequency: one step is 1 Hz Duty factor: one step is 5%.

V.6.3. Work modes (ultrasound)

Continuous mode means an uninterrupted ultrasound wave emission.

Pulsed mode means that ultrasound wave is interrupted at a given pulse frequency and duty factor. Duty factor is a ratio of the emission time to the pulse period.

V.6.4. Treatments in water

Treatment heads are suited for treatments in water.

Treatment heads may be immersed in water up to 2/3 of their length.

IMPORTANT: Do not soak applicator's cable in water.

V.6.5. Starting treatment

In order to start a treatment first set the parameters and then press START STOP. The signalling diode on the probe lights up, timer on it starts counting down and the state of connection of the applicator with the patient is shown.

WARNING: Remember to put the treatment gel on the applicator head.

V.6.6. Monitoring the contact applicator/patient

The device controls state of connection between the front of the treatment head and the patient. It is shown on the screen in percentage. This indication is approximate; it does not show the exact area of contact.

If the contact indication is equal to or higher than 50%, time of treatment is counted down. If there is no contact (or lower than 50%), then:

- ultrasound emission is stopped (but the treatment is not terminated)
- · treatment time is not counted down
- sound signal starts and light diode on the applicator starts flickering
- state of connection is still monitored
- if there is no connection for 1 minute, treatment is stopped and a relevant message shown

If the contact is restored the treatment is automatically continued.

Weak contact may result e.g. from:

- too weak tightening of the treatment head with the patient
- treatment head is touching too small area of the patient's body
- lack of or too little amount of treatment gel
- too much patient hair in the treatment area on the body

V.6.7. Termination of treatment

Treatment ends in one of the following cases:

Time of treatment runs out.

Then the signal diode on the applicator turns off, the timer background turns green and the end of treatment sound signal starts, which may be stopped by pushing any button.

• By pressing the emergency stop . Then the emission is immediately stopped.

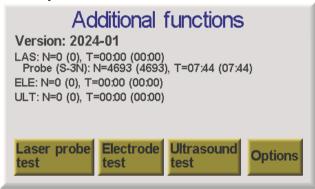
NOTICE: When the end of treatment results from the emergency stop, then in order to continue the treatment it is necessary to switch the device OFF and ON. Using this button interrupts all active treatments.



- Pressing the button START
- Longer than 1 minute break of the contact applicator/patient
- Malfunction was detected in the device or in the applicator treatment is stopped automatically (possible options are described in p. V.10. "Information given by the unit during work"

When the end of treatment results from malfunction, the suitable information appears on the screen and shall stay on until OK is pressed. Necessary actions to remove malfunction should be taken, depending on the kind of malfunction. Assistance of a qualified maintenance technician may be required.

V.6.8. Ultrasonic applicator power test



- There will be additional functions of the device. One of them is the ultrasonic test. Press the "Ultrasound test" button.
- To run the power test, select the ultrasonic applicator under test, position it with its forehead upward and drip water, quite a lot, but so that it does not run off the forehead.



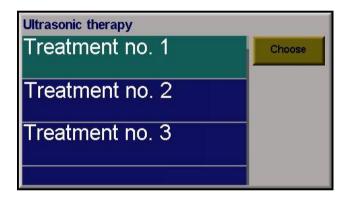
• To run the power test, select the first frequency and observe the effect. Then add water again and select the second frequency. If the probe is working properly, most of the water should be vaporized. The effect is stronger for a frequency of 1 MHz.

V.7. PROGRAM function (build-in treatment parameters)

PROGRAM is a pre-programmed collection of optimal sets of device parameters suitable for selected illnesses. When the button program is pressed, a list of programmed illnesses appears on the screen (arranged according to illness type):





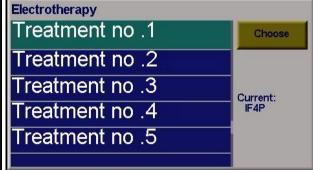


A list of indications is displayed according to the selected treatment.

Use buttons or touch the screen to choose the item. Alternatively you may press the screen and while pressing move your finger up or down for browsing through the list.

The selection is confirmed by pressing "Choose" on the screen or by pressing the button.





You may discontinue using PROGRAM function by pressing BACK or PROGRAM button at any moment.

NOTICE: If no applicator is connected or a treatment is currently active in a channel, then the buttons for program selection are not active for this channel.

V.8. MEMORY function (user's own parameters)

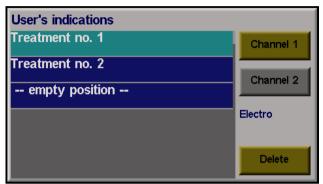
This function allows saving parameters' values which are most often used by the user. You may assign them to illnesses or patient names.

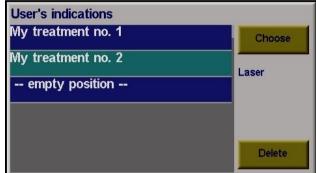
V.8.1. Favourite parameter sets

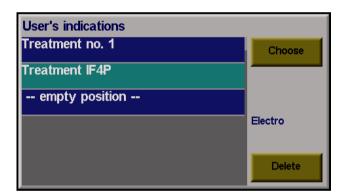
Using the MEMORY function one can create a collection of individual ("favourite") settings. It is possible to make your own settings or to copy the settings from the available programmes. To copy a ready program to MEMORY, select it as in p. V.7. "PROGRAM function" and then save it as in p. V.8.3. "Saving treatment parameters in MEMORY"

V.8.2. Reading the previously saved settings from MEMORY

You can use the treatment previously saved in MEMORY by pressing button. The list of saved items will show up on the screen.







Use ______ buttons or touch the screen to choose the desired item. Alternatively you may press the screen and, while keeping pressed, move your finger up or down to browse through the list. Confirm your selection with the button "Choose".

You may resign from using the MEMORY function by pressing button at any moment.

V.8.3. Saving treatment parameters in MEMORY

To save treatment parameters in **MEMORY**:

- choose treatment parameters when the device is in the edition mode
- press <u>HEMORY</u>; the list of saved items appears on the screen
- Using buttons or touching the screen chose the item "--empty position--"



press ADD button <u>— the window for entering the description shows</u> up



- you may change the position of the cursor with buttons or by touching the screen
- description of the item is entered with the keyboard shown on the screen
- tabs at the lower end of the keyboard mean:
 - CAPS capital letters on/off
 - SPACE inserting space
 - BACKSPACE deleting of last symbol to the left of the cursor
 - NEWLINE adding new line after the cursor

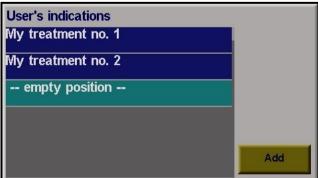
When ready, the description is confirmed by pressing

You may discontinue using **MEMORY** function by pressing button at any moment.

V.8.4. Deleting an item from MEMORY

In order to delete an item from **MEMORY** do the following:

choose item in the list which is to be deleted - with buttons o touching the screen



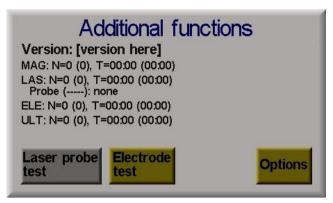
• press **DELETE** on the screen; a window will appear with a request for confirmation



• press YES to delete item or NO to quit deleting

V.9. Additional functions

Press button to access the additional device functions (from the main parameter edition screen).



You may use them to do the following:

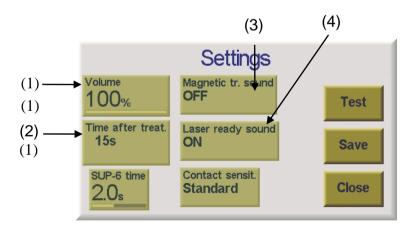
- check the software version
- check the number of performed treatments (does not include the ones interrupted before the set time) and their total time (all treatments and those with the laser applicators separately)

The Numbers and times after the "=" sign concern the period since the date of manufacturing, while the ones provided with parentheses are counted since the last service.

- Start the power test of laser
- Start the electrotherapy electrode test
- Set the sound signal parameters (including the end of treatment signal)
- Set the sensitivity of the ultrasound probe contact detection

V.9.1. Setting (Options)

Pressing "Options" on the "Additional functions" screen calls up the following window:



Description of the fields:

- (1) Setting the sound volume 0 –100%.
- (2) Time of the sound signal after the end of treatment (choose from list): 15 s, 30 s, 1 min, 2 min, not terminated
- (3) Detection sensitivity of the probe/body acoustic contact during the ultrasound treatment
- (4) Lasertherapy sound signal in the 'ready for treatment' phase (ON/OFF)

Touch the field to be changed and use the keys to alter choice.

The field can be chosen directly on the display, or by pressing the key

To check up the sound volume press the **Test** key.

The settings chosen should be accepted with the **Save** key.

To exit the setting window press the Close or BACK key. If there were any changes made that have not been saved, the request for confirmation will appear:



V.9.2. Setting the sensitivity of the ultrasound applicator contact detection Choose "Contact sensitivity" in the Setting window.

The field can be chosen directly on the display, or by means of the key The choice is by indicating the chosen field and pressing keys

The "standard" setting is the most sensitive, it can be changed into less sensitive "medium" and "low" levels.



The "medium" level is half less sensitive than "standard". The "low" level is a quarter of the "standard" level. Lowering sensitivity helps to avoid frequent pauses during treatment because of temporary loss of contact.

To exit this window and save the values do the same as in the preceding section.

V.10. Information given by the unit during work

During treatment, the unit constantly monitors the parameters of the treatment. When an error is detected, all treatments are stopped and one of following messages is shown on the screen.

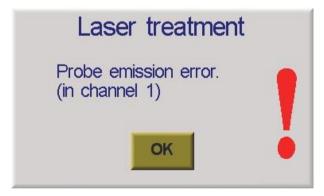
Malfunction of the fan:



Problems with the transmission of laser applicator



• Error of the laser probe emission



• Laser: "Ready for emission" is OFF; No activity for over 1 min.



• The door opened (if the door switch is installed)



Ultrasound: No contact of the ultrasound head with the patient's body



• Ultrasound: the applicator non-operational



This messages can be closed by pressing **OK** and then the device automatically switches over to the parameter edition mode.

NOTICE: Most frequent cause of fault is disconnection or break in applicator's cable. When the error occurs please check the connection of all cables in the sockets on both sides and search for possible damages of the cables. If this does not help, you have to contact an authorised service.

V.11. Helpful general information

A comment on using the touch screen:

IMPORTANT: Use the touch screen with care, because the screen is not resistant to hits or scratches. In particular, do not hit it with sharp objects (like pen or nails). The strength necessary for activating a "button" on the screen is similar to that used when pressing the external keyboard.

The device detects the type of applicator connected.

- The device detects a break in the electrotherapy circuit and signals it with sound. The treatment is not stopped.
- If a break is detected in an ultrasound or a magnetotherapy applicator the treatment is interrupted and an appropriate message displayed.
- The device is designed for a continuous use. It is not necessary to switch it off during breaks between treatments.
- Avoid unnecessary using of the emergency stop.

Electrotherapy

For CV mode:

- You cannot use microcurrents.
- You cannot set "Reverse" polarity.
- Choosing double-channel current (tonolysis, IF4P) turns off CV mode.

For microcurrents:

- You cannot choose CV mode.
- Choosing double-channel current (tonolysis, IF4P) turns off microcurrents.

For 2-channel current (tonolysis, IF4P):

- You cannot choose CV mode.
- You cannot use microcurrents.
- You cannot set "Reverse" polarisation.

In the right-hand channel of electrotherapy:

- You cannot change polarisation (direction of the current flow).
- You cannot set the combined therapy.

V.12. Safety of treatments

WARNING: In the event of any serious incident related to the use of a device, it is essential to report this information to the manufacturer and to the relevant competent authority of the Member State dealing with the safety of medical devices. In Poland, such an authority is:

Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych

Al. Jerozolimskie 181C, 02-222 Warsaw

e-mail: incydenty@urpl.gov.pl

fax: +48 (22) 492 11 29

<u>WARNING:</u> It is necessary to interview the patient about the contraindications against the treatment, before the treatment is started.

<u>WARNING:</u> In case of untypical device behaviour, which may be dangerous to the patient or staff, stop the treatment immediately and follow the guidelines of the chapter VI. "Maintenance".

WARNING: To avoid the risk of electric shock, the appliance must be connected to a mains supply with a protective earthing connection.

WARNING: Do not make any modifications to the device.

WARNING: The use of therapy for patients under the age of 8 years is possible following a positive specialist medical opinion.

<u>IMPORTANT:</u> Treatment applicators (probes and heads) should be protected from shocks and mechanical damage. Applicator damage may be not visible from outside and may result in faulty work.

IMPORTANT: Operating the device in close proximity (up to a few metres) to a source of shortwave or microwave therapy may cause the output signal to become unstable and the device to malfunction.

<u>IMPORTANT:</u> Care should be taken not to transfer bacteria from one patient to another or to the staff. Pay attention to the hygiene of patients and staff. Applicators and eyewear must be properly cleaned and disinfected with proper agent (70% solution of ethyl alcohol or a suitable disinfectant is recommended).

The application of the agent should be checked up in the manufacturer's datasheet. It is also advised to put it to test on a small area of a probe and check on the possible damage after some time (e.g. after 24 hours).

NOTICE: The device must be switched off by setting the power switch in the position "O" after daily treatments.

Additional for lasertherapy

<u>WARNING:</u> The device belongs to the laser Class 3B. Laser ray emitted is dangerous for eyes, both directly, and also if reflected from a mirror-like surface. However, this radiation is harmless for the skin.

<u>WARNING:</u> In case of laser treatment, when the device is switched on, the patient and staff and everybody present in the room must wear protective eyewear.

<u>WARNING:</u> It is forbidden to direct the laser probe at any direction other than the place of treatment and particularly not in the direction of eyeballs.

<u>WARNING:</u> The laser treatments with MULTITRONIC MT-6 should be performed in dedicated premises, so that the third persons would not be endangered by accidental laser emission. All reflecting surfaces (glass, glossy tiles, chromium plated objects, etc.), which could accidentally reflect the laser beam, should be excluded from this premises.

WARNING: No information was found on the use of laser therapy in people with dark skin colour, therefore laser therapy is not recommended for such people.

WARNING: Prior to treatment, ensure that the patient has not used cosmetic or photosensitising medicines (antibiotics, sulfonamides, herbs) in the vicinity of the treatment site.

IMPORTANT: Place the supplied warning labels on the door of the laser treatment room.

Additional for electrotherapy

WARNING: For the patients with lowered sensitivity the current amplitude **must be adjusted** according to the current density and not the patient's sensitivity. This density depends on the shape of electrodes, place of treatment and type of treatment. The exact methodology is described in professional literature. Neglecting those rules can cause the patient to suffer negative consequences, like burn because of too high current. (Particularly important for ionophoresis).

WARNING: Do not perform treatment with electrode without moistured pad – it may cause burns to the patient.

WARNING: Electrodes may be placed only on healthy skin and always with properly moistured pads.

WARNING: Electrodes should be placed on patient when the device is switched on (POWER button in position I). Otherwise, the patient may feel an unpleasant electric shock at switching on the power supply.

WARNING: A patient with an implanted electronic device (e.g. a pacemaker) may not undergo electric current therapy unless a positive specialist medical opinion is obtained.

<u>WARNING:</u> Electrical stimulation should not be used across or over the head, directly over the eyes, covering the mouth, at the front of the neck (especially the carotid sinus), with electrodes crossing over the heart, in the upper back or on the chest.

WARNING: The application of electrodes in the thoracic region increases this risk of cardiac fibrillation.

IMPORTANT: When using electrodes with a surface area of less than 51 cm² (E-A5, E-A10, E-A15, E-A50, E-S50), staff should pay particular attention during treatment, as the density of the set current may exceed the safety limit of 2 mA/cm².

IMPORTANT: Remember that using pads with electrodes is necessary for proper current flow. This is the reason why adequate moist and thickness of pads must be kept.

IMPORTANT: Before the treatment check if the patient did not use ointment in the area of electrode placement and clean the skin if necessary (ointment may cause incorrect current flow). Similarly, excessive hair growth should be shaved in places of electrode placement (thick hair obscures proper current flow).

NOTICE: Cathode (minus) is connected to the red end of cable and anode (plus) is connected to black end of cable.

Additional for ultrasound

<u>WARNING:</u> Before starting treatment it is necessary to make sure the patient has no blood flow disturbances or metal objects in the treatment area. Otherwise internal burns may occur resulting from the tissue density change when blood flow is limited (especially periosteum burn by a "standing wave" effect).

<u>WARNING:</u> It is forbidden to use ECG gel as connecting agent for the treatment head.

IMPORTANT: During treatment with ultrasound head a small part of vibration may be transmitted to holding part of the applicator and to therapist's hand. This exposure is very low and should have no significant effects. Sometimes therapists complain about ailments resulting from work with ultrasound treatment heads but it possibly results from work physiology of hand. People who work long time with ultrasound heads should avoid limb overuse and possible desecration formation. We advise working more with shoulder and systematic relieving of the tension of wrist.

VI. MAINTENANCE

NOTICE: The addresses of authorised service are available at the manufacturer's office (see: the cover of this manual).

VI.1. Checking the proper operation of the device

- The unit should be periodically checked every 12 months throughout the time of exploitation.
- Emitted power of all laser probes and the accuracy of the built-in power meter should be checked every 12 months.
- Laser power meter used should be of the class 10%.

- The checking can be done only by the manufacturer or authorised service having a manufacturer's certificate.
- The periodical technical tests should be made at the user's workplace, because the work environment of the unit has to be checked.

<u>IMPORTANT:</u> If the device fell down, before the next switching on call for the authorised service to inspect the device. There may be invisible damages that can bring about a faulty operation.

VI.2. Proper working environment

Observing the recommendations given below will help keep the device in good technical condition and will assure a long and undisturbed use.

- Power supply mains should be checked systematically, there should be no breaks, sparking or similar disturbances.
- Equipment should not work in humid environment or one with steam, salts, sulphides etc. in the air. Pay attention there are no any rooms for inhalation, hydrotherapy, pools or similar if in vicinity. If you cannot avoid such situation, the room with electrotherapy equipment must be insulated from such influences.
- Work environment should not be dusted or littered, because the fan may get blocked by the accumulated dust and dirt. Break-down of the device may occur, similarly to a PC computer. This may be avoided by systematic (e.g. once a month) cleaning of the fan with a vacuum-cleaner (see VI.3. "Repairs").
- The device should not be heated by an external radiator, heater, direct sunlight etc. Overheated electric devices may break down.

VI.3. Repairs

Should any faulty operation occur, the equipment ought to be delivered to an authorised service having a manufacturer's certificate for such repairs or directly to the manufacturer for check up or repair.

If the mains switch indicating that the device is switched on is not illuminated, have the fuse, located on the rear panel of the device (a spare fuse is provided) checked and replaced if necessary by a qualified service technician.

IMPORTANT: All repairs can be performed only by the manufacturer or authorised service.

NOTICE: When sending equipment to the service or manufacturer, remember to enclose all cables and accessories used with the unit and also a detailed description of failure (conditions of work, features of error etc.), your address and contacts (phone, e-mail).

NOTICE: Check the service authorization certificate for it may not be authorized to conduct specific controls or repairs (concerns especially laser probes).

VI.4. Maintenance and cleaning

The device should be cleaned of accumulating dirt.

- At least once a month clean the fan on the back panel and ventilating holes at the bottom of the device. Turn the power off and remove dust with a vacuum-cleaner, keeping the muzzle for at least 1 min at the apertures.
- Clean the device with a soft moistened cloth or sponge, but not too wet, not to let water inside.
- Protective eyewear should be cleaned with a cloth suitable for normal corrective glasses.

NOTICE: Do not use paint or varnish solvents to clean the device.

NOTICE: The manufacturer of the viscose material used in the electrode pads attached to the device states that this material can be machine-cleaned at 60°C with detergent.

VI.5. Maintenance of electrodes

- Immediately after every treatment, electrodes should be removed from their pouches (pads) and dried up in room temperature.
- During the removal, an electrode should be held by its body and not by the wire to avoid the cable damages.
- Pads and electrodes should be disinfected after each treatment. A 70% ethanol solution or a suitable disinfectant is recommended. The intended use of the disinfectant should be checked in the manufacturer's instructions, or a test should be carried out on a small area and checked after a sufficiently long period of time to ensure that no adverse material changes have occurred (e.g. after 24 hours).
- From time to time (not less than every 7 days), the electrode terminals ought to be inspected, whether they are not loose or damaged.
- The damaged electrodes and cables (loose terminals, dirt, breakings or splitting of wires) can be a source of not dangerous but unpleasant sensations for the patient. Every possible electrode repair should be done by a qualified maintenance technician.

<u>WARNING:</u> Silicone ("rubber") electrodes lose their electric conductivity after some time of use. This time depends on the intensity of usage and for this reason they should be checked periodically e.g. with the function of electrode test (at least once a week).

<u>NOTICE:</u> Do not bind viscose pads when they are dry. It may cause the pouch/pad to break and prohibit its further use.

NOTICE: Never keep the electrodes in wet pouches. Otherwise they lose their effective electric conductivity quickly.

NOTICE: Silicone electrodes should not be used for ionophoresis because they lose electric conductivity quickly and in effect must not be used for further treatments.

VI.5.1. Electrode testing function

MULTITRONIC MT-6 has an electrode testing function for checking the conductivity status. In order to use this function one should touch "Electrode test" field in the additional functions screen. The tested electrode should be connected to the cable in channel 1 (left-hand). Connect only the metal "pin" to the other end of this cable. To test, gently (without pressing) move the pin over the whole electrode surface and observe the indication on the screen. The pin should be moved in parallel lines 5-10 mm apart. Typical electrode shows different conductivity in different areas. Status of the electrode may be concluded from most common results in different areas.

<u>WARNING:</u> One should be careful when an electrode is totally warn out in some areas (outside acceptable level) and acceptable in others. In such a situation the current will flow only through "working" areas. This is not recommended and may cause electric burns.

The results on the screen are presented with values and symbolic colours:

- Green if electrode resistance is up to 500 ohms it is fully operational
- Yellow if electrode resistance is from 501 to 1000 ohms it may be used under condition of stricter control
- Red if electrode resistance is over 1000 ohms it must not be used for treatments because it may cause unpleasant feelings or even burns.



VI.6. Maintenance of applicators

IMPORTANT: The device, and especially applicators, should be protected from shocks, hits and falling which may result in mechanical damage.

IMPORTANT: Periodically (for example everyday before starting treatment) check up the applicator cables for damage. The repairs of the ultrasound or laser cable should be done by an authorised service. For other damages: see p. VI.3. "Repairs".

Laser probe

After each treatment the laser terminals of the probes should be cleaned and disinfected with gauze or cotton slightly moistened with 70% solution of ethyl alcohol. Next treatment may be started after the agent/alcohol dries out.

NOTICE: Protect the lens of probes from scratching.

NOTICE: Laser diodes have limited emission time (2-5 years is typical, depending on the use), therefore one should periodically check the emitted power as described above. Errors in probe work may result from cable breaks or main unit damage. In other cases the diode has to be replaced by the manufacturer.

Ultrasound heads

After each treatment the treatment head should be cleaned of gel and dried with soft cloth. Then after drying it should be disinfected with gauze or cotton slightly moistened with 70% solution of ethyl alcohol. Next treatment may be started after the agent/alcohol dries out. This procedure prevents the microorganism transmission between patients.

VI.7. The most frequent problems in electrotherapy

Most frequent problems:

- difficulties in parameter setting
- inability to set treatment parameters
- too high local current density which may result in unpleasant feelings and even electric burns

When these problems occur check the following:

- whether the pad is not too dry
- whether electrodes evenly adhere to patient's body and are properly pressed
- the electrode conductivity (whether it is not too low)
- whether the cable is not damaged
- whether the patient did not use the ointment at treatment areas (clean it)
- the patient's hair growth (shave, if excessive)

VI.8. Disposal of the warn out equipment

- Predicted exploitation time of the device is 10 years, provided that it is properly used and maintained according to user's manual and put to periodic technical service.
- After this time the device may be still used as long as it is serviced by the authorised service according to its condition. It can be further used if approved by the authorized service or by the manufacturer. Especially service intervals can be shortened in comparison to the nominal ones.
- After the exploitation time is over or end of usage, the device should be handed over for disposal to a company dealing with disposal of electronic equipment, in accordance with current legislation.

VII. MEDICAL DESCRIPTION

<u>WARNING:</u> Recommendation of this manual are of general nature. They should be adjusted individually to every patient.

WARNING: In doubts consult a doctor of appropriate speciality.

<u>WARNING:</u> Treatments with Multitronic MT-6 must be done by a qualified physiotherapist under the supervision of a medical doctor. Otherwise the therapy effects may be limited and the patients may be exposed to the risk of health deterioration.

<u>WARNING:</u> Treatments must be conducted according to the instructions for use and all safety recommendations.

WARNING: The maximum dose of laser radiation should not exceed 2000 mJ/cm².

NOTICE: Evening or night-time magnotherapy should be avoided as patients may have difficulty falling asleep.

VII.1. Intended patient group

The Multitronic MT-6 can be used with patients of all ages, taking into account the counterindications listed below in p. VII.3. "Contraindications".

VII.2. Indications

VII.2.1. Basic indications for lasertherapy

- Rheumatology and musculoskeletal disorders
 - Osteoarthritis
 - Pain reduction in osteoarthritis
 - Osteopenia
 - o Osteoporosis
 - Cervical spondylosis
 - Ankylosing spondylitis
 - Osteoarthritic changes of small joints
 - o Inflammations of the joint capsule
 - Analgesic effects
- Orthopedics and sports medicine
 - Painful shoulder syndrome
 - Painful back syndromes
 - o Inflammation of the lateral epicondyle of the humerus / tennis elbow
 - o Biceps tendonitis
 - Sheath inflammation of the de Quervain's tendon
 - Inflammation of the plantar fascia
 - o Posterior tibial tendon dysfunction
 - Ankle joint sprain
 - Fracture of the wrist bone
 - o Fractures of the radius bone of the arm
 - Fractures of the wrist and hand
 - Delayed healing of bone fractures
 - Temporomandibular joint pain
 - Temporomandibular disorders
 - Chronic discogenic sciatica
 - Analgesic effect
 - Inflammation
 - Flexor tendon injury
 - Spinal cord injury

- Neurological conditions and neuropathies
 - Ulnar neuropathy
 - Trigeminal neuralgia
 - Radiculopathy
 - o Peripheral neuropathic pain
 - Neuropathic pain
 - o Pain associated with hemiplegia
 - o Carpal tunnel syndrome
 - o Morton's neuroma
- Dentistry and oral disorders
 - Analgesic effect after orthodontic procedures
 - Dentin pain hypersensitivity
 - Caries
 - Gingivitis
 - Periapical healing of the tooth
 - Alveolar inflammation
 - Delayed eruption of the tooth
 - o Reducing inflammation of the oral mucosa caused by chemoradiotherapy
 - Traumatic ulcers associated with dentures
- Dermatology and tissue regeneration
 - Ulcers
 - Diabetic foot ulcers
 - Venous ulcers
 - Oral ulcers
 - Bedsores
 - o Burns
 - Wound healing
 - Burn wounds of the lower extremities
 - Hypertrophic scars after burns
 - Post-surgical scars
 - Stretch marks (striae)
 - o Inflammatory acne
 - Horizontal wrinkles on the neck
 - Purulent skin diseases
 - Herpes
- Gynecology
 - Bartholin's gland cyst or abscess
 - Atrophy of the vulva and vagina
 - Lichen sclerosus of the vulva
- · Laryngology and upper respiratory tract disorders
 - o Chronic rhinosinusitis
 - o Earditis / otitis media
- Urology and diseases of the male reproductive system
 - Chronic prostatitis (prostadinitis)

VII.2.2. Basic indications for ultrasound therapy

- Rheumatology and musculoskeletal disorders
 - Osteoarthritis
 - Osteoarthritis of the hip joint
 - Osteoarthritis of the knee joint
 - Ankylosing spondylitis (Bechterev's disease)
 - o Fibromyalgia
 - Lower back pain

- Sciatica
- · Orthopedics and sports medicine
 - Pain syndromes such as:
 - Spinal pain syndromes
 - Tennis elbow
 - Shoulder pain
 - Myofascial pain
 - o Heel bone spurs
 - o Achilles tendonitis
 - o Condition after an injury to the ankle joint
 - Lateral epicondylitis
 - Tendonitis
 - Adhesive capsulitis
 - Tendinopathy
 - Quervain's tendon sheath inflammation
 - Carpal tunnel syndrome
- Dentistry and oral disorders
 - Temporomandibular joint pain and trismus
 - Masticatory myalgia
- Dermatology and tissue regeneration
 - Treatment of bedsores
 - Venous leg ulcers
 - Shin ulceration
- Neurological disorders
 - Treatment of nodules in multiple sclerosis

VII.2.3. Basic indications for electrotherapy

- Rheumatology and musculoskeletal disorders
 - Osteoarthritis of the knee joints
 - Raynaud's syndrome
 - o Atherosclerotic disease of the peripheral arteries
 - Osgood-Schlatter disease
 - Degenerative kyphosis of the lumbar spine
 - Skeletal muscle atrophy and weakness
 - o Chronic, non-specific low back pain
 - Lumbar disc herniation / sciatica syndrome
 - Cervical disc herniation
 - Cervical spine pain associated with cervical disc herniation
 - Lumbar spine pain
 - Supportive in chronic neck pain
 - o Shoulder pain
 - Fibriomyalgia
- Orthopedics and sports medicine
 - Subacromial tunnel syndrome
 - Tennis elbow
 - Chronic instability of the ankle joint (after dislocations, sprains)
 - o Injury to the metacarpophalangeal joint
 - Stiffened thumbs after injury to the ulnar collateral ligament of the metacarpophalangeal joint
 - Pain due to femoral head necrosis / Perthes disease
- Neurological conditions and neuropathies
 - Hemiplegic neuralgia
 - o Bell's palsy / facial nerve palsy

- o Chronic migraine
- Unilateral spastic cerebral palsy
- Peripheral nerve regeneration
- Neuropathic pain
- Spinal cord injuries
- Dentistry and oral disorders
 - Temporomandibular joint function syndrome
 - o Dysphagia
- Rehabilitation and recovery of function
 - o Physical and functional support for patients with pneumonia
 - Urinary incontinence
 - Functional bowel constipation
 - Diseases of the trunk periphery
 - Pain relief during childbirth
 - Myofascial pain
- Dermatology and tissue regeneration
 - Varicose leg ulcers
- Others:
 - Lowering hormone levels in thyroid therapy
 - o lontophoresis: introduction of therapeutically acting ions into tissues (painkillers, anti-inflammatory, antibacterial, antiviral, antifungal, vitamins, minerals and others exact indications depend on the drug).

VII.3. Contraindications

VII.3.1. Contraindications to lasertherapy

- Application to the eyeballs
- Pregnancy. Do not treat uterus region. Other regions may be treated, yet special attention is needed.
- Haemorrhage. Do not treat patients with haemorrhage because intensification of symptoms may occur.
- Cancer. Do not treat undiagnosed changes. It is possible to treat patients with cancer during palliative therapy as analgesic therapy - with patient's agreement after being informed.
- Thyroid gland. Do not treat thyroid gland.
- Immunosuppressive therapy. It is not recommended to use laser biostimulation with this therapy.

VII.3.2. Contraindications to ultrasound therapy

- Cancers and conditions after their surgical removal (consent of an oncologist required)
- Pregnancy
- Bleeding disorders
- · Circulatory failure
- Heart arythmia
- Pacemaker
- Peripheral blood supply disorders
- Thrombophlebitis
- · Acute inflammatory processes and febrile conditions
- Severe general condition and exhaustion
- Incomplete bone growth
- Conditions after X-ray therapy

- The presence in the tissues of metal foreign bodies
- Severe vegetative neurosis
- Unexplained neuralgia
- Advanced vascular calcification
- Skin changes, especially in the course of infectious diseases
- Generalized atherosclerosis and atherosclerotic conditions of the limbs
- Bronchiectasis
- Gastrointestinal bleeding

Ultrasound must not be used for safety reasons in some areas of the body: the area of the heart and cardiac segment, lungs, parenchymal organs of the abdominal cavity, brain, testicles, eyes, bones (and especially epiphyses) in children and adolescents, the area of the medulla oblongata (the maximum height of sounding is the C4 segment of the cervical spine) and areas adjacent to the area where the laminectomy (excision of the vertebral arch) was performed. The clusters of lymph nodes - armpits, elbows, popliteal and groin must not be treated also.

VII.3.3. Contraindications to electrotherapy

- Purulent inflammations
- Blemishes
- Febrile conditions
- Inflammation of the skin
- Epidermis defects at the treatment site
- Excessive sensitivity to electric current
- Muscle spasmodic paralysis
- · Patients with active implants
- Pregnancy

VII.3.3.1 Particular contraindications to ionophoresis

- General contraindications are the same as for other electrotherapeutic treatments
- Moreover, when using ionophoresis drugs that cause allergies, such as procaine, lidocaine, iodine, antibiotics, an intradermal allergy test should be performed before starting the treatment. It should also be remembered that ions that are beneficial in the underlying disease may be contraindicated due to the patient's other conditions
- Cancer diseases and cancer risk states

VII.4. Side effects

Side effects that may rarely occur at the irradiation site during laser therapy include: a warm sensation, burning, moderate pain, rash, appearance of blisters on the skin, changes in skin pigmentation, numbness, itching. Burns can also occur if equipment is used inappropriately. There have also been isolated cases of fatigue, palpitation, hazy vision, difficulty moving, dizziness and headaches after laser therapy treatments and keratitis following exposure to the cornea.

Side effects that can occur during electrotherapy include skin irritation and pain at the site of application of the currents. Burns may also occur if equipment is used inappropriately.

Side effects that have been reported during ultrasound therapy include burns, the appearance of blisters on the skin, rashes and swelling, tingling, pain, difficulty moving, and tinnitus. If cavitation is too intense, cell death and internal bleeding can occur.

VIII. METHODOLOGY OF TREATMENTS

<u>WARNING:</u> Treatments with Multitronic MT-6 must be done by a qualified physiotherapist. Otherwise the therapy effects may be limited and the patients and the staff may be exposed to the risk of health damage.

NOTICE: Treatments must be conducted according to the user's manual and especially all safety recommendations described in it must be observed.

VIII.1. Methodology of lasertherapy treatment

Dose:

WARNING: The maximal dose should not exceed 2000 mJ/cm².

For acute states the energy dose range is (50 ÷500) mJ/cm².

For chronic states the energy dose range is (500 ÷ 2000) mJ/cm².

Detailed power doses adequate for various illnesses can be found in the enclosed bibliography. The time of a single treatment is up to 20 minutes – depending on the size of area treated (usually shorter). The number of treatments is 5-60, depending on type of illness.

Irradiation techniques may be divided into contact and non-contact.

These may be further divided into: point, line and area treatment.

The contact technique means direct placement of lens on the spot treated. The non-contact technique means that lens is 2 or less centimetres over the area treated, without touching the area.

Whenever possible, the contact technique should be used, because the radiation energy loses are lower.

- Surface irradiation is used when illness concerns the surface of the patient's body.
- Line irradiation is used when the ill area is shaped as a straight or a broken line.
- Point irradiation is used for a single spot or a series of small spots (including the acupuncture points).

VIII.2. Methodology of ultrasound treatment

In ultrasound therapy, it is customary to use a frequency of 1 MHz for deeper tissues and 3 MHz for surface tissues, in accordance with half-depth rule. From the point of view of the methodology of performing the procedure, the appropriate selection of this parameter is crucial for its effectiveness. In practice, each ultrasound treated area must be assessed for the depth of the target tissue, the abundance of surrounding tissue, and the proximity of the bone. The values given in the table of indications are the proposed base values, but each person applying ultrasound should individually select all treatment parameters, including the carrier frequency.

VIII.3. Methodology of electrotherapy treatment

The effectiveness of treatments using electric currents depends on:

- Proper selection of electrodes
- Electrode application sites
- The intensity of the applied currents
- The frequency of the applied currents
- The duration of the procedure
- Number of treatments

VIII.3.1. Electrodes

Proper choice of electrodes depends on many factors, most importantly place of application. Using small electrodes allows for greater current density at lower current as

compared to larger electrodes. Flat metal aluminium foil electrodes of large sizes are used for treatments of large areas of body. In order to avoid unpleasant feeling during treatment it is most important that pads (sponge covers) are thick enough and adhere to skin. Pads should be thoroughly moistened with water or physiologic salt solution. Electrodes are fastened in place with elastic straps and are further pressed with a weight which easily adheres to the body shape (e.g. a sand bag).

NOTICE: Electrodes supplied with the device have the following area:

 $E-A 10 - 10 \text{ cm}^2$; $E-A 50 - 50 \text{ cm}^2$; $E-A 75 - 75 \text{ cm}^2 \text{ ect.}$

NOTICE: For ionophoresis use metal electrodes as the active ones (with medication).

VIII.3.2. Preparation for treatment

- Preparation of the patient for treatment with electric current is the same as for other physiotherapy treatments.
- Before treatment it is necessary to inform the patient about his possible feelings. Examples of the patient's sensations: tingling, stinging, pressure, etc.
- Skin should be cleaned in place of treatment.
- Choice of electrodes depends on the size of area for treatment electrodes should be as large as possible.
- Pads/pouches under electrodes should be thick enough (around 4 mm) and thoroughly moistened with boiled water or physiologic salt solution.
- Electrodes should be firmly fastened to patient's body using elastic bandage, rubber or velcro straps, yet taking care to avoid blood flow obstruction.

VIII.4. i/t curve

VIII.4.1. Procedure for curve determination

Multitronic MT-6 can perform the electrodiagnostics procedure. It allows to complete data needed for the i/t curve ploting and automatically calculates a set of indexes.

Electrodiagnostics using this curve enables the quantitative evaluation of the conditions of muscles and of the progress of therapy.

Electrode placement. Electrodiagnostics uses the electrotherapy channel. The active electrode (1-3 cm diameter) is connected to negative pole (minus) and is placed on the motor point of diagnosed muscle. The passive electrode (plus) (should be much larger) is connected to positive pole (red end of cable) and is placed on skin sufficiently away from the active one.

Electrodiagnostics procedure consists of measuring the current intensity which brings about the muscle contraction for various pulse widths. There are two series of pulses used:

Rectangular shaped with times of pulse as follows:

1000 ms, 500 ms, 200 ms, 100 ms, 50 ms, 20 ms, 10 ms, 5 ms, 2 ms, 1 ms, 500 μ s, 200 μ s, 100 μ s

Triangular shaped with times of pulse as follows:

1000 ms, 500 ms, 200 ms, 100 ms, 50 ms, 20 ms, 10 ms, 5 ms, 2 ms, 1 ms

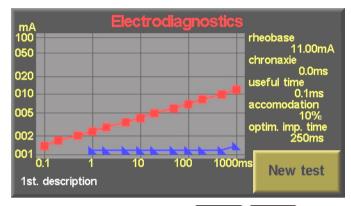
Measurement of the current (resulting in muscle contraction for a given pulse width) is based on consecutive generation of pulses of the same width, every next one of which has slightly higher current value. The break between the pulses is from 0.5 to a few seconds (adjustable). When the therapist or patient notices the muscle reaction, the value of the current is saved by pressing the button on the device.

The consecutive current values differ from each other by ca. 20%. From 1 mA to 100 mA there are 26 steps.

Results of the last 5 electrodiagnostics procedures are saved in non-volatile memory and can be checked even after turning the device off.

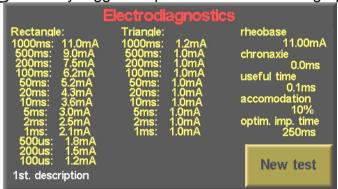
VIII.4.2. Performing the i/t curve determination

Electrodiagnostics procedure may be selected the same way as the type of current (Ediag). After choosing Ediag, the screen of browsing the formerly saved results will appear



The surveyed results may be browsed with

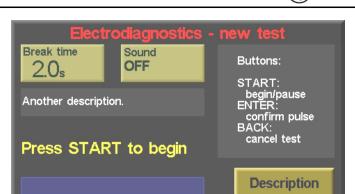
With button NEXT one may toggle the presentation between graphic and tabular.



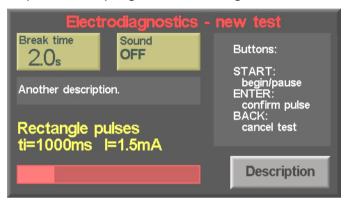
- Pressing "New test" starts a new electrodiagnostic procedure.
- If there is no free memory place for saving results, a message window will show up,
 " Make new test go. The oldest will be erased"



- Touch "Description" and enter the test description with the screen keyboard. If no description has been entered, then when START/STOP is pressed the device will automatically switch to it.
- The current emission begins by pressing START/STOP on the keyboard



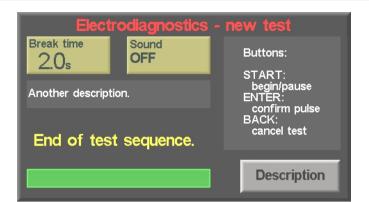
During generation of pulses the progress bar changes colour to red



 Pressing START/STOP during the pulse generation causes a temporary pause in current flow. The progress bar changes to green. The pulse generation can be reactivated by pressing the START/STOP again.



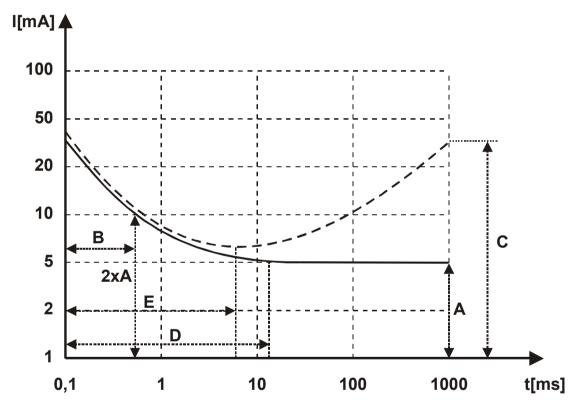
- The break time between consecutive series of pulses may be adjusted. The sound signal may be turned on or off. These functions may also be changed during procedure.
- After starting the procedure the device automatically generates consecutive pulses.
 The patient's tissue reaction is confirmed by pressing ENTER.
- Electrodiagnostics procedure may be cancelled at any moment by pressing BACK. In such a case the results will not be saved in memory.
- After all pulses were generated / confirmed "End of test sequence." message will appear on the screen. After 5 s. the screen will turn to the results browsing.



VIII.4.3. i/t curve

An example of an i/t curve (for a healthy muscle) is shown below.

Continuous line shows the results for rectangular pulses. The dashed line is for triangular pulses. Both axes are in logarithmical scale.



VIII.4.4. Definitions of indexes

Multitronic MT-6 automatically calculates values of the following indexes (marked on the picture above as A,B,C,D,E):

- Rheobase = A value of current for rectangular shape of 1000ms width [mA]
- Chronaxie = B
 pulse width of rectangular shape for current value of double rheobase [ms]
- Accommodation coefficient = $\frac{C}{A} \cdot 100\%$ ratio of current for triangular shape to that of rectangular for pulse width=1000 ms [%]

- Useful time = D
 the lowest pulse width of rectangular pulse for which current value is equal to
 rheobase [ms]
- Optimal pulse time = E
 pulse width of triangle shape of the lowest current intensity [ms]

VIII.4.5. Interpretation of electrodiagnostics results

i/t curve. An exemplary drawing of i/t curve for a healthy muscle is shown in p. VII.5.3 "i/t curve". For partially or entirely denervated muscle the curve moves right and up – towards higher currents and longer pulses.

Accommodation coefficient. This coefficient shows the muscle ability of adaptation (called accommodation) to slowly increasing currents for triangle pulses. For normal nervous-muscular excitability its value is usually 3 to 6. The values lower than 3 show decreased adaptation of muscle, which means the muscle is damaged. The value close to or equal to 1 means a complete degeneration. The values over 6 occur for the vegetative neurosis.

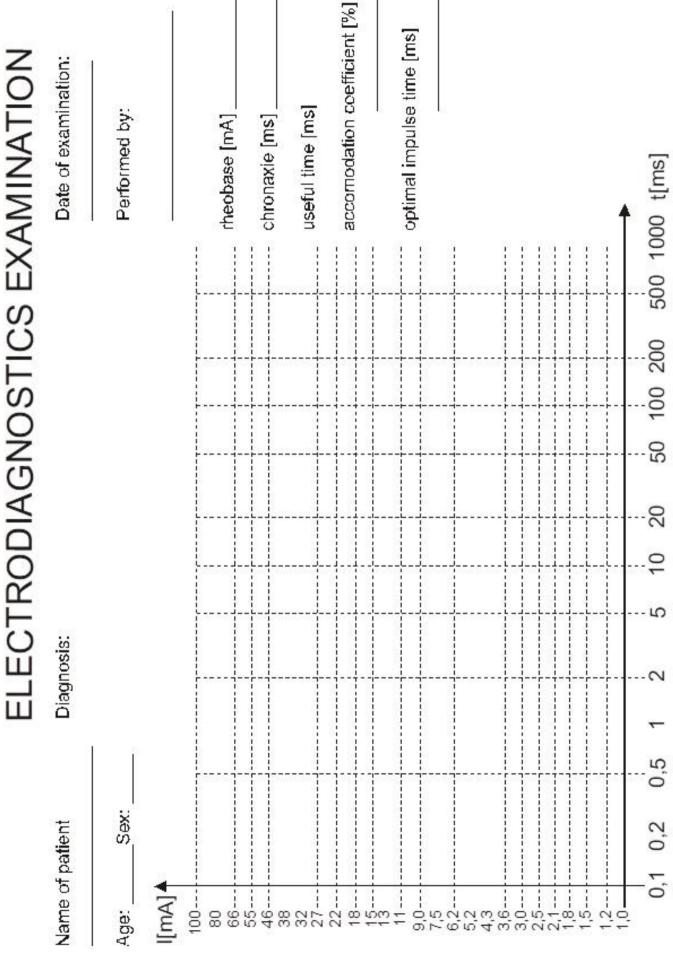
Chronaxie. This indicator shows excitability of the muscle. Its value is higher for lower excitability.

Comparing the results in the following tests (e.g. in a weekly cycle) we may assume an improvement of the muscle state, if the i/t curve moves towards lower currents and shorter pulse widths, the accommodation coefficient rises (in range of 3-6) and chronaxie drops down.

VIII.4.6. i/t curve card

On the next page there is an exemplary electrodiagnostics blank form for i/t curve drawing. For better clarity it is useful to draw the results for triangular and rectangular pulses in different colours.

Both axes of the graph are on a logarithmic scale. On both axes there are values of respectively times and currents generated by the device during the electrodiagnostics procedure, resulting in marking points of the graph at the intersection of dashed lines.



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Please fill in the following questionnaire. Your opinions are very helpful in fulfilling your expectations concerning our equipment.

USER'S QUESTIONNAIRE

Please pick your answer and mark it with an X.

D	evice's	type		MT-6		Device's	number			
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2.	What i	s the re	liability of the	device durir	ng use?					
	/ery eliable		Unreliable		Average		Rather reliable		Reliable	
3.	How d	o you gr	rade easiness o	f operating	this device?					
	/ery fficult		Difficult		Average		Easy		Very easy	
4.	Does t	he devi	ce meet expect	ations?						
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5.			tion provided in rmation?	n the instru	ctions for use	and on the	device cle	ar and does	it provide the	!
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6.	If the o	levice h	as been service	ed (repaired	d) please evalu	uate the qua	llity of the	service:		
Ver	y poor		Poor		Average		Good		Very good	
Has	not bee	n servic	ed							
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		Yes		No		I cannot	decide			
	 C	an the	content of the	ne instruc	tions be imp	oroved? If	so, what	should be	changed?	
		Yes		No		I cannot			Č	

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b/	Other notes or Please name ti	n the use of the o	device: e person filling	in this questi	ionnaire:
b/	Other notes or Please name ti	n the use of the o	device: e person filling	in this questi	ionnaire:

Thank you for filling in this questionnaire.

Pease send filled questionnaire by e-mail: office@eie.com.pl
or by post: EiE, 05–402 Otwock, ul. Zaciszna 2, Poland

